

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK**

LABORERS 17 HEALTH BENEFIT FUND,

Plaintiff,

CIVIL ACTION NO.: _____

-vs-

PURDUE PHARMA, L.P.;
PURDUE PHARMA, INC.;
THE PURDUE FREDERICK COMPANY, INC.;
TEVA PHARMACEUTICALS INDUSTRIES, LTD.;
TEVA PHARMACEUTICALS USA, INC.;
CEPHALON, INC.;
JOHNSON & JOHNSON;
JANSSEN PHARMACEUTICALS, INC.;
ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS,
INC., n/k/a JANSSEN PHARMACEUTICALS, INC.;
JANSSEN PHARMACEUTICA, INC., n/k/a JANSSEN
PHARMACEUTICALS, INC.;
NORAMCO, INC.;
ENDO HEALTH SOLUTIONS, INC.;
ENDO PHARMACEUTICALS, INC.;
QUALITEST PHARMACEUTICALS, INC.;
ALLERGAN PLC, f/k/a ACTAVIS PLC;
WATSON PHARMACEUTICALS, INC., n/k/a ACTAVIS, INC.;
WATSON LABORATORIES, INC.;
ACTAVIS LLC;
ACTAVIS PHARMA, INC., f/k/a WATSON PHARMA, INC.;
MALLINCKRODT PLC;
MALLINCKRODT LLC;
MCKESSON CORPORATION;
CARDINAL HEALTH INC.;
AMERISOURCEBERGEN DRUG CORPORATION;
ABBOTT LABORATORIES, INC.;
RUSSELL PORTENOY;
PERRY FINE;
SCOTT FISHMAN; and
LYNN WEBSTER;

Defendants.

COMPLAINT AND DEMAND FOR JURY TRIAL

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The Plaintiff, LABORERS 17 HEALTH BENEFIT FUND, having been duly authorized to institute and maintain the above-captioned action by its Board of Trustees, and by and through its undersigned counsel, hereby sues the Defendants, PURDUE PHARMA, L.P., PURDUE PHARMA, INC., THE PURDUE FREDERICK COMPANY, INC., TEVA PHARMACEUTICALS INDUSTRIES, LTD., TEVA PHARMACEUTICALS USA, INC., CEPHALON, INC., JOHNSON & JOHNSON, JANSSEN PHARMACEUTICALS, INC., ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., n/k/a JANSSEN PHARMACEUTICALS, INC., JANSSEN PHARMACEUTICA, INC., n/k/a JANSSEN PHARMACEUTICALS, INC., NORAMCO, INC., ENDO HEALTH SOLUTIONS, INC., ENDO PHARMACEUTICALS, INC., QUALITEST PHARMACEUTICALS, INC., ALLERGAN PLC, f/k/a ACTAVIS PLC, WATSON PHARMACEUTICALS, INC., n/k/a ACTAVIS, INC., WATSON LABORATORIES, INC., ACTAVIS LLC, ACTAVIS PHARMA, INC., f/k/a WATSON PHARMA, INC., MALLINCKRODT PLC, MALLINCKRODT LLC, MCKESSON CORPORATION, CARDINAL HEALTH INC., AMERISOURCEBERGEN DRUG CORPORATION, ABBOTT LABORATORIES, INC., RUSSELL PORTENYOY, PERRY FINE, SCOTT FISHMAN, and LYNN WEBSTER, for damages and alleges as follows:

I. INTRODUCTION

1. The opioid addiction crisis has become a national public health emergency impacting nearly every community across all 50 states.¹ According to the U.S. Centers for Disease Control and Prevention (“CDC”), the nation has been swept up in an opioid-induced public health epidemic.² Since 2000, more than 300,000 Americans have lost their lives to an opioid overdose.

¹ *The President’s Commission on Combating Drug Addiction and the Opioid Crisis*. 2017, Nov. 21. https://www.whitehouse.gov/sites/whitehouse.gov/images/Final_Report_Draft_11-1-2017.pdf.

² CDC, *New data show continuing opioid epidemic in the United States*. 2016, Dec. 16. <https://www.cdc.gov/media/releases/2016/p1216-continuing-opioid-epidemic.html>.

See id. The CDC found that in 2015 more than 52,000 people died from a drug overdose; of those, 33,091 (63.1 percent) involved a prescription or illicit opioid. *Id.* In fact, the CDC found that New York State ranked first in the country for states with the greatest increases in synthetic opioid death rates from 2014 – 2015. *See id.* (finding that New York experienced a 135.7% increase from 2014 – 2015).

2. Opioids³ include brand-name drugs like OxyContin and Percocet and generics like oxycodone and hydrocodone. They are derived from or possess properties similar to opium and heroin, and, as such, they are highly addictive and dangerous and therefore are regulated by the United States Food and Drug Administration (“FDA”) as controlled substances.⁴

3. Opioids provide effective treatment for short-term post-surgical and trauma-related pain, and for palliative end-of-life care. They are approved by the FDA for use in the management of moderate to severe pain where use of an opioid analgesic is appropriate for more than a few days.

4. Opioid analgesics, however, are widely diverted and improperly used, and the widespread abuse of opioids has resulted in the national epidemic of opioid overdose deaths and addictions.⁵ The opioid epidemic is “directly related to the increasingly widespread misuse of

³ The term “opioid,” as used herein, refers to the entire family of opiate drugs including natural, synthetic and semi-synthetic opiates.

⁴ Since passage of the Controlled Substances Act (“CSA”) in 1970, opioids have been regulated as controlled substances. As controlled substances, they are categorized in five schedules, ranked in order of their potential for abuse, with Schedule I being the most dangerous. The CSA imposes a hierarchy of restrictions on prescribing and dispensing drugs based on their medicinal value, likelihood of addiction or abuse, and safety. Opioids generally had been categorized as Schedule II or Schedule III drugs. Schedule II drugs have a high potential for abuse, have a currently accepted medical use, and may lead to severe psychological or physical dependence. Schedule III drugs are deemed to have a lower potential for abuse, but their abuse still may lead to moderate or low physical dependence or high psychological dependence.

⁵ *See* Nora D. Volkow & A. Thomas McLellan, *Opioid Abuse in Chronic Pain— Misconceptions and Mitigation Strategies*, 374 N. Eng. J. Med. 1253 (2016).

powerful opioid pain medications.”⁶

5. At all times material, Defendants knew that controlled studies of the safety and efficacy of opioids were limited to short-term use (*i.e.*, not longer than 90 days) in managed settings (*e.g.*, hospitals) where the risk of addiction and other adverse outcomes was significantly minimized. Indeed, the FDA has expressly recognized that there have been no long-term studies demonstrating the safety and efficacy of opioids for long-term use.⁷

6. The Defendants knew, and have known for years, that opioids were addictive⁸ and subject to abuse, particularly when used long-term for chronic non-cancer pain (pain lasting three months or longer, hereinafter referred to as “chronic pain”), and should not be used except as a last resort. Defendants also knew that, with prolonged use, the effectiveness of opioids wanes, requiring increases in doses to achieve pain relief and markedly increasing the risk of significant side effects and addiction.⁹

7. Despite the foregoing knowledge, in order to expand the market for opioids and realize blockbuster profits, Defendants sought to create a false perception of the safety and efficacy of opioids in the minds of medical professionals and members of the public that would encourage the use of opioids for longer periods of time and to treat a wider range of problems, including such common aches and pains as lower back pain, arthritis, and headaches.

8. Defendants accomplished that false perception through a coordinated, sophisticated, and highly deceptive and unfair marketing campaign that began in the late

⁶See Robert M. Califf et al., A Proactive Response to Prescription Opioid Abuse, 374 N. Eng. J. Med. 1480 (2016).

⁷ Letter from Janet Woodcock, M.D., Dir., Ctr. for Drug Eval. & Res., to Andrew Kolodny, M.D., Pres. Physicians for Responsible Opioid Prescribing, Re docket No. FDA-2012-P-0818 (Sept. 10, 2013).

⁸See Diagnostic and Statistical Manual of Mental Disorders (5th ed. 2013) (“DSM-V”) (Addiction is a spectrum of substance use disorders that range from misuse and abuse of drugs to addiction.). The term “addiction,” as used herein, refers to the entire range of substance abuse disorders. Individuals suffer negative consequences wherever they fall on the substance use disorder continuum.

⁹ See, *e.g.*, Russell K. Portenoy, *Opioid Therapy for Chronic Nonmalignant Pain: Current Status*, 1 Progress in Pain Res. & Mgmt., 247-287 (H.L. Fields and J.C. Liebeskind eds., 1994).

1990s, became more aggressive in or about 2006, and continues to the present.

9. Defendants engaged in a practice and pattern of gross negligence and reckless disregard for the health and safety of consumers using prescription opioids by flooding the pharmaceutical market with dramatic increases in prescription thresholds without justification. The Defendants, individually and collectively, provided millions of opioid prescription drugs to countless pharmacies nationwide, and specifically throughout New York, without accountability and despite the Defendants' knowledge of suspicious orders.

10. Defendants, individually and collectively, knowing that long-term opioid use causes addiction, misrepresented the dangers of long-term opioid use to physicians, pharmacists, and patients by engaging in a campaign to minimize the risks of, and to encourage, long-term opioid use.

11. Defendants' marketing campaign has been extremely successful in expanding opioid use. Since 1999, the amount of prescription opioids sold in the U.S. has nearly quadrupled.¹⁰ In 2010, 254 million prescriptions for opioids were filled in the U.S. – enough to medicate every adult in America around the clock for a month. In that year, 20% of all doctors' visits resulted in the prescription of an opioid (nearly double the rate in 2000).¹¹ While Americans represent only 4.6% of the world's population, they consume 80% of the opioids supplied around the world and 99% of the global hydrocodone supply.¹² By 2014, nearly two million Americans either abused or were dependent on opioids.¹³

¹⁰ CDC, Injury Prevention & Control: Opioid Overdose, Understanding the Epidemic. Available at: <http://www.cdc.gov/drugoverdose/epidemic/index.html>.

¹¹ M. Daubresse, et al., Ambulatory Diagnosis and Treatment of Nonmalignant Pain in the United States, 2000-2010, 51(10) Med. Care 870-78 (2013).

¹² L. Manchikanti, et al., Therapeutic Use, Abuse, and Nonmedical Use of Opioids: A Ten- Year Perspective, 13 Pain Physician 401-435 (2010).

¹³ CDC, Injury Prevention & Control: Opioid Overdose, Prescription Opioids. Available at: <http://www.cdc.gov/drugoverdose/opioids/prescribed.html>.

12. Defendants' campaign has been extremely profitable for them generating billions of dollars from addictive prescription opioids. In 2012 alone, opioids generated \$8 billion in revenue for drug companies.¹⁴ Of that amount, \$3.1 billion went to Defendant Purdue for its OxyContin sales.¹⁵

13. Defendants' marketing campaign has been extremely harmful to Americans. Overdoses from prescription pain relievers are a driving factor in a 15-year increase in opioid overdose deaths. Deaths from prescription opioids have also quadrupled since 1999. From 2000 to 2014 nearly half a million-people died from such overdoses. Seventy-eight Americans die every day from an opioid overdose.¹⁶

14. In 2012, an estimated 2.1 million people in the United States suffered from substance use disorders related to prescription opioid pain relievers.¹⁷ Between 30% and 40% of long-term users of opioids experience problems with opioid use disorders.¹⁸

15. Opioid addiction and overdose have reached epidemic levels over the past decade. On March 22, 2016, the FDA recognized opioid abuse as a "public health crisis" that has a "profound impact on individuals, families and communities across our country."¹⁹ Defendants' marketing campaign has failed to achieve any material health care benefits. Since 1999, there

¹⁴ B. Meier & B. Marsh, *The Soaring Cost of the Opioid Economy*, N.Y. Times (June 22, 2013).

¹⁵ K. Eban, *Purdue Pharma's Painful Medicine*, Fortune Magazine (Nov. 9, 2011).

¹⁶ CDC, Injury Prevention & Control: Opioid Overdose, Understanding the Epidemic, *supra*.

¹⁷ Substance Abuse and Mental Health Services Administration, *Results from the 2012 National Survey on Drug Use and Health: Summary of National Findings*, NSDUH Series H- 46, HHS Publication No. (SMA) 13-4795. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2013.

¹⁸ J. Boscarino et al., Risk factors for drug dependence among out-patients on opioid therapy in a large US health-care system, 105(10) *Addiction* 1776 (2010); J. Boscarino et al., Prevalence of Prescription Opioid-Use Disorder Among Chronic Pain Patients: Comparison of the DSM-5 vs. DSM-4 Diagnostic Criteria, 30(3) *Journal of Addictive Diseases* 185 (2011).

¹⁹ FDA announces enhanced warnings for immediate-release opioid pain medications related to risks of misuse, abuse, addiction, overdose and death.

<http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm491739.htm>.

has been no overall change in the amount of pain that Americans report.²⁰

16. The National Institutes of Health (“NIH”) not only recognizes the opioid abuse problem, but also identifies Defendants’ “aggressive marketing” as a major cause: “Several factors are likely to have contributed to the severity of the current prescription drug abuse problem. They include drastic increases in the number of prescriptions written and dispensed, greater social acceptability for using medications for different purposes, and *aggressive marketing by pharmaceutical companies*.”²¹ As shown below, the “drastic increases in the number of prescriptions written and dispensed” and the “greater social acceptability for using medications for different purposes “ are not really independent causative factors but are in fact the direct result of “the aggressive marketing by pharmaceutical companies.”

17. The rising numbers of persons addicted to opioids have led to significantly increased health care costs as well as a dramatic increase of social problems, including drug abuse and diversion²² and the commission of criminal acts to obtain opioids throughout the United States. The CDC recently estimated that the total “economic burden” of prescription opioid misuse alone in the United States is \$78.5 billion a year, including the costs of health care, lost productivity, addiction treatment, and criminal justice involvement.²³ Consequently, public health and safety throughout the United States has been significantly and negatively impacted due to the misrepresentations and omissions by Defendants regarding the appropriate uses and risks

²⁰ CDC, Injury Prevention & Control: Opioid Overdose, Understanding the Epidemic, *supra*.

²¹ America’s Addiction to Opioids: Heroin and Prescription Drug Abuse. Available at http://www.drugabuse.gov/about-nida/legislative-activities/testimony-to-congress/2015/americas-addiction-to-opioids-heroin-prescription-drug-abuse#_ftn2 (accessed March 31, 2016) (emphasis added).

²² According to the CDC, when prescription medicines are obtained or used illegally, it is called “drug diversion.”

²³ Florence, C. S., Zhou, C., Luo, F. & Xu, L. The Economic Burden of Prescription Opioid Overdose, Abuse, and Dependence in the United States, 2013. Medical Care 54, 901-906, doi:10.1097/MLR.0000000000000625 (2016).

of opioids, ultimately leading to widespread inappropriate use of the drug.

18. From 1990 to 2015 the average consumption of hydrocodone nationwide increased by 300%. In the same period, there was a 500% increase in the number of Emergency Department visits attributed to hydrocodone abuse with 19,221 visits estimated in 2000.²⁴

19. Deaths from prescription opioids have quadrupled since 1999. From 2000 to 2014 nearly half a million-people died from such overdoses. In 2015 over 33,000 Americans died as a result of an opioid overdose,²⁵ and an estimated 2 million people in the United States suffered from substance use disorders related to prescription opioid pain medicines (including fentanyl), and 591,000 suffered from a heroin use disorder (not mutually exclusive).²⁶ Prescription opioid misuse is a significant risk factor for heroin use; 80 percent of heroin users first misuse prescription opioids.²⁷

20. The dramatic increase in opioid prescriptions to treat common chronic pain conditions has resulted in a population of addicts who seek drugs from doctors. When turned down by one physician, many of these addicts deploy increasingly desperate tactics—including doctor shopping, use of aliases, and criminal means—to satisfy their cravings, cravings which Defendants first fostered then fueled.

21. New York is currently experiencing an epidemic of opioid-related overdose and death. People with opioid addiction are at high risk of overdose and death. Opioid-related

²⁴ http://www.crchealth.com/addiction/drug-addiction-rehab/drug-addiction-rehab-2/home-2/hydrocodone_addiction/

²⁵ Rudd, R. A., Seth, P., David, F. & Scholl, L. Increases in Drug and Opioid-Involved Overdose Deaths — United States, 2010–2015. MMWR Morb. Mortal. Wkly. Rep. 65, 1445-1452, doi:10.15585/mmwr.mm655051e1 (2016).

²⁶ Substance Abuse and Mental Health Services Administration National Survey on Drug Use and Health 2015 Detailed Tables. (2016).

²⁷ Muhuri, P. K., Gfroerer, J. C. & Davies, M. C. (CBHSQ [Center for Behavioral Health Statistics and Quality] Data Review, 2013).

deaths in between 2014 and 2015 in New York, had the greatest increase by state in the entire country. This recent rate of increase is several times faster than anything seen here before.

22. While opioid-related deaths have been on the rise across the country during that period, the situation in New York has become especially worrying. In one way or another — through deaths, nonfatal overdoses, or disruptions to jobs, marriages, families, and neighborhoods — every community in New York has been impacted by this growing crisis.

23. The Defendant pharmaceutical manufacturers, distributors, promoters and sellers have earned billions of dollars peddling their addictive and life-threatening prescription opioid drugs while systematically and intentionally misleading doctors, patients, federal and state regulators, and health and welfare insurers and funds about the true risk of opioid addiction. The Defendants have engaged in an intentional, decades-long pattern of unfair and deceptive acts relating to the efficacy of their respective opioid drugs, intentionally diminishing the associated health hazards and conspiring with key opinion leaders to increase their sales and profits despite the known risks and dangerous propensity of their drugs.

24. The Defendant pharmaceutical manufactures intentionally overstated the benefits and downplayed the risks of the use of their opioids and aggressively marketed (directly and through key opinion leaders) these drugs to physicians and the Defendant distributors failed to monitor, detect, investigate, refuse and report suspicious orders of prescription opiates as required under the Controlled Substances Act.

25. Plaintiff brings this suit against the Defendants because it has been victimized by the fraudulent and misleading scheme perpetrated by these drug manufacturers, distributors, promoters and sellers. These companies and individuals put profits ahead of patient safety and the immeasurable toll the opioid epidemic has caused in New York, and specifically the losses sustained by Plaintiff. The Plaintiff has paid for a substantial amount of the opioid-related health care costs including prescription, addiction and rehabilitation, overdose and alternative drug treatments incurred by its members.

26. As a direct and foreseeable consequence of Defendants' wrongful conduct, Plaintiff has incurred and continues to incur costs for opioid prescriptions in excess of those they would have otherwise incurred, payments for their insureds' treatment for opioid addiction, and payments for emergency hospital visits for their insureds' including payments for Naloxone Hydrochloride (Narcan) resulting from opioid abuse and overdose. Defendants' misrepresentations regarding the safety and efficacy of long-term opioid use proximately caused injury to Plaintiff. Accordingly, Plaintiff seeks compensation and reimbursement for these losses, as well as potential attorneys' fees and costs, and punitive damages as allowable.

II. THE PARTIES

A. PLAINTIFF

27. Plaintiff, LABORERS 17 HEALTH BENEFIT FUND (hereinafter referred to as "Plaintiff" or "Laborers 17"), is an employee health and welfare benefit fund established pursuant to and in accordance with Section 302 of the Labor-Management Relations Act of 1947, as amended, 29 U.S.C. Section 186. Laborers 17 is established and maintained by employers engaged in commerce and by an employee organization representing employees engaged in commerce and in industry and activity affecting commerce within the meaning of 29 U.S.C. Section 1002(1) – (3). Laborers 17 has its office and regular place of business located at 451A Little Britain Road, Newburgh, New York 12550.

28. Plaintiff has standing to recover damages incurred as result of Defendants' actions and omissions. Plaintiff has standing to bring claims pled herein, *inter alia*, to bring claims under the federal RICO statute, pursuant to 18 U.S.C. § 1961(3) ("persons" include entities which can hold legal title to property) and 18 U.S.C. § 1964 ("persons" have standing). Plaintiff also has standing to bring claims pled herein pursuant to New York General Business Law Section 349 ("GBL § 349").

29. At all times material to this cause of action, Plaintiff has paid and/or provided

reimbursement for some or the entire purchase price on behalf of its members for prescription opioids, which are manufactured, marketed, promoted, sold, and/or distributed by the Defendants. Plaintiff has sustained injury as a direct and proximate result of Defendants' illegal and wrongful conduct alleged herein and seeks recovery of any and all costs, damages or losses sustained as a result of the provision of care, services and/or supplies, including, but not limited to, the delivery of prescription opioid medications, treatments, hospitalizations, addiction and rehabilitation treatment, overdose or other opioid-related services.

B. DEFENDANTS

1. Manufacturer Defendants

30. The Manufacturer Defendants are defined below. At all relevant times, the Manufacturer Defendants have packaged, distributed, supplied, sold, placed into the stream of commerce, labeled, described, marketed, advertised, promoted and purported to warn or purported to inform prescribers and users regarding the benefits and risks associated with the use of the prescription opioid drugs. The Manufacturer Defendants, at all times, have manufactured and sold prescription opioids without fulfilling their legal duty to prevent diversion and report suspicious orders.

31. Defendant, PURDUE PHARMA L.P., is a limited partnership organized under the laws of Delaware with its principal place of business in Stamford, Connecticut.

32. Defendant, PURDUE PHARMA INC., is a Delaware corporation with its principal place of business in Stamford, Connecticut.

33. Defendant, THE PURDUE FREDERICK COMPANY, INC., is a Delaware corporation with its principal place of business in Stamford, Connecticut.

34. Defendants, PURDUE PHARMA, L.P., PURDUE PHARMA, INC., THE PURDUE FREDERICK COMPANY, INC. (hereinafter collectively referred to "Purdue"), at all

times material, were authorized to conduct and conducted business in the State of Connecticut.

35. Purdue manufactures, promotes, sells, and distributes opioids nationally, and in this district, including the following:

Table 1. Purdue Opioids

Drug Name	Chemical Name	Schedule²⁸
OxyContin	Oxycodone hydrochloride extended release	Schedule II
MS Contin	Morphine sulfate extended release	Schedule II
Dilaudid	Hydromorphone hydrochloride	Schedule II
Dilaudid-HP	Hydromorphone hydrochloride	Schedule II
Butrans	Byprenorphine	Schedule III
Hysingla ER	Hydrocodone bitrate	Schedule II
Targiniq ER	Oxycodone hydrochloride and naloxone	Schedule II

36. OxyContin is Purdue's largest-selling opioid. Since 2009, Purdue's national annual sales of OxyContin have fluctuated between \$2.47 billion and \$2.99 billion, up four-fold from 2006 sales of \$800 million. OxyContin constitutes roughly 30% of the entire market for analgesic drugs (*i.e.*, painkillers).

37. Defendant, TEVA PHARMACEUTICALS USA, INC. ("Teva USA"), is a Delaware corporation with its principal place of business in North Wales, Pennsylvania. Teva USA is a wholly owned subsidiary of TEVA PHARMACEUTICAL INDUSTRIES, LTD. ("Teva Ltd."), an Israeli corporation.

38. Defendant, CEPHALON, INC. ("Cephalon, Inc."), is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. In 2011, Teva Ltd. acquired Cephalon, Inc.

39. Teva USA and Cephalon, Inc. (collectively, "Cephalon") work together to manufacture, promote, distribute and sell both brand name and generic versions of the opioids nationally, and in this district, including the following:

Table 2. Cephalon Opioids

²⁸ See note 4, *supra*.

Drug Name	Chemical Name	Schedule
Actiq	Fentanyl citrate	Schedule II
Fentora	Fentanyl citrate	Schedule II

40. Teva USA was in the business of selling generic opioids, including a generic form of OxyContin from 2005 to 2009 nationally and in this district.

41. Teva Ltd., Teva USA, and Cephalon, Inc. work together closely to market and sell Cephalon products in the United States.²⁹ Teva Ltd. conducts all sales and marketing activities for Cephalon in the United States through Teva USA and has done so since its October 2011 acquisition of Cephalon. Teva Ltd. and Teva USA hold out Actiq and Fentora as Teva products to the public. Teva USA sells all former Cephalon branded products through its “specialty medicines” division. The FDA-approved prescribing information and medication guide, which is distributed with Cephalon opioids, discloses that the guide was submitted by Teva USA, and directs physicians to contact Teva USA to report adverse events.

42. All of Cephalon’s promotional websites, including those for Actiq and Fentora, display Teva Ltd.’s logo. Teva Ltd.’s financial reports list Cephalon’s and Teva USA’s sales as its own, and its year-end report for 2012 – the year immediately following the Cephalon acquisition – attributed a 22% increase in its specialty medicine sales to “the inclusion of a full year of Cephalon’s specialty sales,” including *inter alia* sales of Fentora®.³⁰ Through interrelated operations like these, Teva Ltd. operates in the United States through its subsidiaries Cephalon and Teva USA. The United States is the largest of Teva Ltd.’s global markets, representing 53% of its global revenue in 2015, and, were it not for the existence of Teva USA and Cephalon,

²⁹ E.g., ACTIQ, <http://www.actiq.com/> (displaying logo at bottom-left).

³⁰ Teva Ltd., Annual Report (Form 20-F) 62 (Feb. 12, 2013), http://annualreports.com/HostedData/AnnualReportArchive/t/NASDAQ_TEVA_2012.pdf.

Inc., Teva Ltd. would conduct those companies' business in the United States itself. Upon information and belief, Teva Ltd. directs the business practices of Cephalon and Teva USA, and their profits inure to the benefit of Teva Ltd. as controlling shareholder. Teva Pharmaceutical Industries, Ltd., Teva Pharmaceuticals USA, Inc., and Cephalon, Inc. are referred to as "Cephalon."

43. Defendant, JOHNSON & JOHNSON ("J&J") is a New Jersey corporation with its principal place of business in New Brunswick, New Jersey.

44. Defendant, JANSSEN PHARMACEUTICALS, INC. ("JANSSEN PHARMACEUTICALS") is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of J&J.

45. Janssen Pharmaceuticals, Inc. was formerly known as Ortho-McNeil- Janssen Pharmaceuticals, Inc., which in turn was formerly known as Janssen Pharmaceutica, Inc.

46. Defendant, ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. ("OMP"), now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey.

47. Defendant, JANSSEN PHARMACEUTICA, INC. ("JANSSEN PHARMACEUTICA"), now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey.

48. NORAMCO, INC. ("Noramco") is a Delaware company headquartered in Wilmington, Delaware and was a wholly owned subsidiary of J&J until July 2016. NORAMCO, Inc. is licensed by the Pennsylvania Department of Health as a manufacturer or repackager/labeler of prescription drugs and controlled substances.

49. J&J is the only company that owns more than 10% of Janssen Pharmaceuticals stock. Upon information and belief, J&J controls the sale and development of Janssen Pharmaceuticals drugs and Janssen Pharmaceuticals profits inure to J&J's benefit.

50. J&J, Janssen Pharmaceuticals, OMP, Janssen Pharmaceutica and Normaco

(collectively, “Janssen”) are or have been engaged in the manufacture, promotion, distribution, and sale of opioids nationally and in in this district, including the following:

Table 3. Janssen Opioids

Drug Name	Chemical Name	Schedule
Duragesic	Fentanyl	Schedule II
Nucynta ³¹	Tapentadol extended release	Schedule II
Nucynta ER	Tapentadol	Schedule II

51. Together, Nucynta and Nucynta ER accounted for \$172 million in sales in 2014. Prior to 2009, Duragesic accounted for at least \$1 billion in annual sales.

52. Defendant, ENDO HEALTH SOLUTIONS, INC. (“EHS”), is a Delaware corporation with its principal place of business in Malvern, Pennsylvania.

53. Defendant, ENDO PHARMACEUTICALS, INC. (“EPI”), is a wholly owned subsidiary of EHS and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania.

54. EHS and EPU (collectively, “ENDO”) manufacture, promote, distribute and sell opioids nationally and in this district, including the following:

Table 4. Endo Opioids

Drug Name	Chemical Name	Schedule
Opana ER	Oxymorphone hydrochloride extended release	Schedule II
Opana	Oxymorphone hydrochloride	Schedule II
Percodan	Oxymorphone hydrochloride and aspirin	Schedule II
Percocet	Oxymorphone hydrochloride and acetaminophen	Schedule II

55. Opioids made up roughly \$403 million of Endo’s overall revenues of \$3 billion in 2012. Opana ER yielded revenue of \$1.15 billion from 2010 to 2013, and it accounted

³¹ Depomed, Inc. acquired the rights to Nucynta and Nucynta ER from Janssen in 2015.

for 10% of Endo's total revenue in 2012. Endo also manufactures and sells generic opioids, both directly and through its subsidiary, Defendant QUALITEST PHARMACEUTICALS, INC., including generic oxycodone, oxymorphone, hydromorphone, and hydrocodone products.

56. WATSON PHARMACEUTICALS, INC. acquired ACTAVIS INC. in October of 2012 and the combined company adopted the name Actavis, Inc. as of January 2013 before finally settling on Actavis PLC in October 2013. WATSON LABORATORIES, INC. is a Nevada Corporation with its principal place of business in Corona, California, and is a wholly owned subsidiary of ALLERGAN PLC (f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc. ACTAVIS PHARMA, INC (f/k/a Actavis, Inc.) is a Delaware corporation with its principal place of business in New Jersey and was formerly known as WATSON PHARMA, INC. ACTAVIS, LLC. is a Delaware Limited Liability Company with its principal place of business in Parsippany, New Jersey. (Allergan PLC, Actavis PLC, Actavis Inc., Actavis LLC, Actavis Pharma Inc., Watson Pharmaceuticals Inc., Watson Pharma Inc., and Watson Laboratories Inc. are referred to as "Actavis").

57. Actavis manufactures, promotes, sells and distributes Opioids, including the branded drugs Kadian and Norco, a generic version of Kadian, and generic versions of Duragesic and Opana throughout the United States, including New York, and in this district. Actavis acquired the rights to Kadian from King Pharmaceuticals, Inc., on December 30, 2008 and began marketing Kadian in 2009.

58. MALLINCKRODT, PLC is an Irish public limited company headquartered in Staines-upon-Thames, United Kingdom, with its U.S. headquarters in St. Louis, Missouri.

59. MALLINCKRODT, LLC is a limited liability company organized and existing under the laws of the State of Delaware, and is registered with the New York Secretary of State to do business in New York. Since 2013, Mallinckrodt, LLC has been a wholly owned subsidiary of Mallinckrodt, plc. Prior to 2013, Mallinckrodt, LLC was a wholly-owned subsidiary of the Irish public limited company Covidien PLLC (formerly known as Tyco Healthcare). Mallinckrodt, plc and Mallinckrodt, LLC are referred to as "Mallinckrodt."

60. Mallinckrodt manufactures, markets, and sells drugs in the United States including generic oxycodone, of which it is one of the largest manufacturers, and opioids sold since at least June 2009 under the brand names Exalgo (hydromorphone), Xartemis (oxycodone/acetaminophen) and Roxicodone (oxycodone) (known by the street names “M,” “roxies/roxys” or “blues”). In July 2017 Mallinckrodt agreed to pay \$35 million to settle allegations brought by the Department of Justice that it failed to detect and notify the DEA of suspicious orders of controlled substances.

2. Distributor Defendants.

61. The Distributor Defendants also are defined below. At all relevant times, the Distributor Defendants have distributed, supplied, sold, and placed into the stream of commerce the prescription opioids, without fulfilling the fundamental duty of wholesale drug distributors to detect and warn of diversion of dangerous drugs for non-medical purposes. The Distributor Distributors universally failed to comply with federal and/or state law. The Distributor Defendants are engaged in “wholesale distribution,” as defined under state and federal law. Plaintiff alleges the unlawful conduct by the Distributor Distributors is responsible for the volume of prescription opioids plaguing Plaintiff’s Community.

62. Defendant MCKESSON CORPORATION (McKesson) is a Delaware corporation with its principal place of business in San Francisco, California.

63. For fiscal year ended March 31, 2017, McKesson generated revenues of \$198.5 Billion.

64. In its 2017 Annual Report, McKesson states that it “partner[s] with pharmaceutical manufacturers, providers, pharmacies, governments and other organizations in healthcare to help provide the right medicines, medical products and healthcare services to the right patients at the right time, safely and cost-effectively.”³²

³² McKesson 2017 Annual Report found at:

65. According to the 2017 Annual Report, McKesson “pharmaceutical distribution business operates and serves thousands of customer locations through a network of 27 distribution centers, as well as a primary redistribution center, two strategic redistribution centers and two repackaging facilities, serving all 50 states and Puerto Rico.”³³

66. McKesson is the largest pharmaceutical distributor in the United States.

67. McKesson does substantial pharmaceutical business in New York and has more than 40,000 customers nationally.

68. Defendant CARDINAL HEALTH INC. (Cardinal”) is an Ohio corporation with its principal place of business in Dublin, Ohio.

69. In 2016, Cardinal generated revenues of \$121.5 billion.

70. Cardinal does substantial pharmaceutical business in Ohio.

71. Defendant AMERISOURCE BERGEN CORPORATION (“Amerisource”) is a Delaware corporation with its principal place of business in Chesterbrook, Pennsylvania.

72. According to its 2016 Annual Report, Amerisource is “one of the largest global pharmaceutical sourcing and distribution services companies, helping both healthcare providers and pharmaceutical and biotech manufacturers improve patient access to products and enhance patient care.”³⁴

73. Amerisource does substantial pharmaceutical business in New York

74. ABBOTT LABORATORIES is a domestic BCA organized under the laws of the State of Illinois with its principal place of business in Abbott Park, Illinois. ABBOTT LABORATORIES, INC., is an Illinois corporation with its principal place of business in Abbott Park, Illinois. (Collectively “Abbott”).

75. Abbott was primarily engaged in the promotion and distribution of Opioids

investor.mckesson.com/sites/mckesson.investorhq.businesswire.com/files/report/file/2017_McKesson_A

³³ *Id.*

³⁴ Amerisource 2016 Annual Report found at:

<http://www.amerisourcebergen.com/investor/phoenix.zhtml?c=61181&p=irol-irhome>

nationally, and in the State of New York, due to a co-promotional agreement with Defendant Purdue. Pursuant to that agreement, between 1996 and 2006, Abbott actively promoted, marketed, and distributed Purdue's Opioid products as set forth above.

76. Abbott, as part of the co-promotional agreement, helped make OxyContin into the largest selling Opioid in the nation. Under the co-promotional agreement with Purdue, the more Abbott generated in sales, the higher the reward. Specifically Abbott received 25 to 30 percent of all net sales for prescriptions written by doctors its sales force called on. This agreement was in operation from 1996-2002, following which Abbott continued to receive a residual payment of 6 percent of net sales up through at least 2006.

77. With Abbott's help, sales of OxyContin went from a mere \$49 million in its first full year on the market to \$1.6 billion in 2002. Over the life of the co-promotional agreement, Purdue paid Abbott nearly half a billion dollars.

78. In 2007 Purdue settled criminal and civil charges against it for misbranding OxyContin and agreed to pay the United States \$635 million. At the time, this was one of the largest settlements with a drug company for marketing misconduct.

79. Defendants McKesson, Cardinal, Amerisource and Abbott (collectively "Distributor Defendants") are the three largest opioid distributors in the United States, and in the State of New York.

80. The Distributor Defendants purchased opioids from manufacturers, such as the Pharmaceutical Defendants, and sold them to pharmacies, which in turn sold them and were paid by Plaintiff.

81. The Distributor Defendants played an integral role in distributing opioids to employees and/or members of Plaintiff.

82. The Distributor Defendants owe a duty under federal law (21 USCA §823, 21 CFR 1301.74) to monitor, detect, investigate, refuse to fill, and report suspicious orders of prescription opioids.

83. The Distributor Defendants were each on notice that the controlled substances they

distributed were susceptible to abuse and overuse and were not effective for long-term use.

84. The Distributor Defendants were each on notice that there was an alarming and suspicious increase in opioid distribution to retailers within the State of New York.

85. As entities involved in the distribution of opioid medications, Distributor Defendants were engaged in abnormally and/or inherently dangerous activity and had a duty of care under Federal law.

86. The Distributor Defendants had a duty to monitor suspicious or alarming orders of opioid pharmaceuticals and to report suspicious orders to the proper authorities and governing bodies, including the Drug Enforcement Agency (DEA).

87. The Distributor Defendants failed in their duty to take action to prevent or reduce the distribution of these drugs.

88. The Distributor Defendants were in a unique position and had a duty to monitor, report, or otherwise limit the flow of these drugs throughout the State of New York.

89. The Distributor Defendants were warned in 2006 and 2007 by the DEA about their responsibility to avoid filling suspicious orders.

90. The Distributor Defendants, in the interest of their own massive profits, intentionally failed in this duty.

91. The DEA has repeatedly taken administrative action to force compliance:

- a. On April 24, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the AmerisourceBergen Orlando, Florida distribution center alleging failure to maintain effective controls against diversion of controlled substances. On June 22, 2007, AmerisourceBergen entered into a settlement which resulted in the suspension of its DEA registration;
- b. On November 28, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Auburn, Washington Distribution Center ("Auburn Facility") for failure to maintain effective controls against diversion of hydrocodone;
- c. On December 5, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Lakeland, Florida Distribution Center ("Lakeland Facility") for failure to maintain effective

controls against diversion of hydrocodone;

- d. On December 7, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Swedesboro, New Jersey Distribution Center (“Swedesboro Facility”) for failure to maintain effective controls against diversion of hydrocodone;
- e. On January 30, 2008, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Stafford, Texas Distribution Center (“Stafford Facility”) for failure to maintain effective controls against diversion of hydrocodone;
- f. On May 2, 2008, McKesson Corporation entered into an Administrative Memorandum of Agreement (“2008 MOA”) with the DEA which provided that McKesson would “maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders required by 21 CFR §1301.74(b), and follow the procedures established by its Controlled Substance Monitoring Program”;
- g. On September 30, 2008, Cardinal Health entered into a Settlement and Release Agreement and Administrative Memorandum of Agreement with the DEA related to its Auburn Facility, Lakeland Facility, Swedesboro Facility and Stafford Facility. The document also referenced allegations by the DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances at its distribution facilities located in McDonough, Georgia; Valencia, California; and Denver, Colorado;
- h. On February 2, 2012, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Lakeland, Florida Distribution Center for failure to maintain effective controls against diversion of oxycodone;
- i. On December 23, 2016, Cardinal Health agreed to pay a \$44 million fine to the DEA to resolve the civil penalty portion of the administrative action taken against its Lakeland, Florida Distribution Center; and
- j. On January 5, 2017, McKesson Corporation entered into an Administrative Memorandum Agreement with the DEA wherein it agreed to pay a \$150,000,000 civil penalty for violation of the 2008 MOA, as well as failure to identify and report suspicious orders at its facilities in Aurora, CO, Aurora, IL, Delran, NJ, LaCrosse, WI., Lakeland, FL, Landover, MD, LaVista, NE, Livonia, MI, Methuen, MA, Santa Fe Springs, CA, Washington Courthouse, OH, and West Sacramento, CA.

92. The Distributor Defendants are members of the Healthcare Distribution

Management Association (“HDMA”). The HDMA created “Industry Compliance Guidelines”, which stressed the critical role of each member of the supply chain in distributing controlled substances. The HDMA guidelines provided that “[a]t the center of a sophisticated supply chain, Distributors are uniquely situated to perform due diligence in order to help support the security of controlled substances they deliver to their customers.”

93. The extraordinary increase in the volume of opioid pain medications distributed to New York retailers should have put the Distributor Defendants on notice to investigate and report such orders.

94. The Distributor Defendants delivered an excessive and unreasonable amount of opioid pain medications to retailers in the State of New York, which was a proximate cause of Plaintiff paying for inappropriate opioid prescriptions.

95. The Distributor Defendants knew or should have known that they were distributing levels of opioid medications that far exceeded the legitimate needs of the State of New York, including to employees and/or members of Plaintiff.

96. The Distributor Defendants paid their sales force bonuses and commissions on the sale of most or all of the highly addictive opioid pain medications.

97. The Distributor Defendants made substantial profits from the opioids paid for by Plaintiff.

98. By the actions and inactions described above, the Distributor Defendants showed a reckless disregard for the safety of the employees and/or members of the Plaintiff.

3. Key Opinion Leader Defendants

99. Russell Portenoy, M.D., is an individual residing in New York. Defendant Portenoy is a physician licensed to practice medicine in the State of New York. Dr. Portenoy was instrumental in promoting opioids for sale and distribution nationally and in the State of New York.

100. Perry Fine, M.D., is an individual residing in Utah. Dr. Fine was instrumental in promoting opioids for sale and distribution nationally and in the State of New York.

101. Scott Fishman, M.D., is an individual residing in California. Dr. Fishman was

instrumental in promoting opioids for sale and distribution nationally and in the State of New York.

102. Lynn Webster, M.D., is an individual residing in Utah. Dr. Fine was instrumental in promoting opioids for sale and distribution nationally and in the State of New York.

III. JURISDICTION AND VENUE

103. This Complaint was filed as an original action in this District.

104. This Court has subject matter jurisdiction under 28 U.S.C. § 1331 based upon the federal claims asserted under the Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. § 1961, *et seq.* (“RICO”). This Court has supplemental jurisdiction over Plaintiff’s state law claims pursuant to 28 U.S.C. § 1367 because those claims are so related to Plaintiff’s federal claims that they form part of the same case or controversy.

105. This Court also has jurisdiction over this action in accordance with 28 U.S.C. § 1332(a), because the Plaintiff is a “citizen” of State of New York and several of the named Defendants are citizens of different states, and the amount in controversy exceeds the sum or value of \$75,000, exclusive of interest and costs.

106. This Court has personal jurisdiction over Defendants because they conduct business in the State, purposefully direct or directed their actions toward the State, some or all consented to be sued in the State by registering an agent for service of process, they consensually submitted to the jurisdiction of the State when obtaining a manufacturer or distributor license, and because they have the requisite minimum contacts with the State necessary to constitutionally permit the Court to exercise jurisdiction.

107. This Court also has personal jurisdiction over all of the defendants under 18 U.S.C. 1965(b). This Court may exercise nation-wide jurisdiction over the named Defendants where the “ends of justice” require national service and Plaintiff demonstrates national contacts. Here, the interests of justice require that Plaintiff be allowed to bring all members of the nationwide

RICO enterprise before the court in a single trial. *See, e.g., Iron Workers Local Union No. 17 Insurance Fund v. Philip Morris Inc.*, 23 F. Supp. 2d 796 (1998); *Butcher's Union Local No. 498 v. SDC Invest., Inc.*, 788 F.2d 535, 539 (9th Cir. 1986).

108. Venue is proper in this District pursuant to 28 U.S.C. § 1391 and 18 U.S.C. §1965, because a substantial part of the events or omissions giving rise to the claim occurred in this District and each Defendant transacted affairs and conducted activity that gave rise to the claim of relief in this District. 28 U.S.C. § 1391(b); 18 U.S.C. §1965(a).

IV. FACTS RELEVANT TO ALL CAUSES OF ACTION

A. THE PAIN-RELIEVING AND ADDICTIVE PROPERTIES OF OPIOIDS

109. The pain-relieving properties of opium have been recognized for millennia. So has the magnitude of its potential for abuse and addiction. Opioids are related to illegal drugs like opium and heroin.

110. During the Civil War, opioids, then known as "tinctures of laudanum," gained popularity among doctors and pharmacists for their ability to reduce anxiety and relieve pain – particularly on the battlefield – and they were popularly used in a wide variety of commercial products ranging from pain elixirs to cough suppressants to beverages. By 1900, an estimated 300,000 people were addicted to opioids in the United States,³⁵ and many doctors prescribed opioids solely to avoid patients' withdrawal. Both the numbers of opioid addicts and the difficulty in weaning patients from opioids made clear their highly addictive nature.

111. Due to concerns about their addictive properties, opioids have been regulated at the federal level as controlled substances by the U.S. Drug Enforcement Administration

³⁵ Substance Abuse and Mental Health Services Administration, Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs, Treatment Improvement Protocol (TIP Services), No. 43 (2005).

(“DEA”) since 1970. The labels for scheduled opioid drugs carry black box warnings of potential addiction and “[s]erious, life-threatening, or fatal respiratory depression,” as the result of an excessive dose.

112. Studies and articles from the 1970s and 1980s also made clear the reasons to avoid opioids. Scientists observed negative outcomes from long-term opioid therapy in pain management programs; opioids’ mixed record in reducing pain long-term and failure to improve patients’ function; greater pain complaints as most patients developed tolerance to opioids; opioid patients’ diminished ability to perform basic tasks; their inability to make use of complementary treatments like physical therapy due to the side effects of opioids; and addiction. Leading authorities discouraged, or even prohibited, the use of opioid therapy for chronic pain.

113. To take advantage of the lucrative market for chronic pain patients, each defendant developed a well-funded marketing scheme based on deception. Each defendant used both direct marketing and unbranded advertising disseminated by seemingly independent third parties to spread false and deceptive statements about the risks and benefits of long term opioid use. Such statements benefitted not only themselves and the third-parties who gained legitimacy when Defendants repeated those statements, but also other Defendants and opioid manufacturers. These statements were not only unsupported by, or contrary to the scientific evidence, they were also contrary to pronouncements by and guidance from the FDA and CDC based on that evidence. They also targeted susceptible prescribers and vulnerable patient populations.

114. Defendants, through their own marketing efforts and publications and through their sponsorship and control of patient advocacy and medical societies and projects, caused deceptive materials and information to be placed into the marketplace, including to prescribers, patients, and third-party payors nationwide and in this district. These promotional messages were intended to and did encourage patients to ask for, doctors to prescribe, and payors to pay for

chronic opioid therapy.

115. Doctors are the gatekeepers for all prescription drugs so, not surprisingly, Defendants focused the bulk of their marketing efforts, and their multi-million-dollar budgets, on the professional medical community. Particularly because of barriers to prescribing opioids, which are regulated as controlled substances, Defendants knew doctors would not treat patients with common chronic pain complaints with opioids unless doctors were persuaded that opioids had real benefits and minimal risks. Accordingly, Defendants did not disclose to prescribers, patients, TPP's, or the public that evidence in support of their promotional claims was inconclusive, non-existent or unavailable. Rather, each Defendant disseminated misleading and unsupported messages that caused the target audience to believe those messages were corroborated by scientific evidence. As a result, doctors nationwide and in this district began prescribing opioids long-term to treat chronic pain – something that most never would have considered prior to Defendants' campaign.

116. Drug company marketing materially impacts doctors' prescribing behavior.³⁶ Doctors rely on drug companies to provide them with truthful information about the risks and benefits of their products, and they are influenced by their patients' requests for particular drugs and payors' willingness to pay for those drugs.

117. Defendants spent millions of dollars to market their drugs to prescribers and

³⁶ See, e.g., P. Manchanda & P. Chintagunta, *Responsiveness of Physician Prescription Behavior to Salesforce Effort: An Individual Level Analysis*, 15 (2-3) Mktg. Letters 129 (2004) (detailing has a positive impact on prescriptions written); I. Larkin, *Restrictions on Pharmaceutical Detailing Reduced Off-Label Prescribing of Antidepressants and Antipsychotics in Children*, 33(6) Health Affairs 1014 (2014) (finding academic medical centers that restricted direct promotion by pharmaceutical sales representatives resulted in a 34% decline in on-label use of promoted drugs); see also A. Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 99(2) Am J. Pub. Health 221 (2009) (correlating an increase of OxyContin prescriptions from 670,000 annually in 1997 to 6.2 million in 2002 to a doubling of Purdue's sales force and trebling of annual sales calls).

patients and meticulously tracked their return on that investment. In one recent survey published by the AMA, even though nine in ten general practitioners reported prescription drug abuse to be a moderate to large problem in their communities, 88% of the respondents said they were confident in their prescribing skills, and nearly half were comfortable using opioids for chronic non-cancer pain.³⁷ These results are directly due to Defendants' fraudulent marketing campaign.

118. As described in detail below, Defendants:

- a. misrepresented the truth about how opioids lead to addiction;
- b. misrepresented that opioids improve function;
- c. misrepresented that addiction risk can be managed;
- d. misled doctors, patients, and payors through the use of misleading terms like "pseudoaddiction;"
- e. falsely claimed that withdrawal is simply managed;
- f. misrepresented that increased doses pose no significant additional risks;
- g. falsely omitted or minimized the adverse effects of opioids and overstated the risks of alternative forms of pain treatment.

119. Defendants' misrepresentations were aimed at doctors, patients, and third-party payors.

120. Underlying each of Defendants' misrepresentations and deceptions in promoting the long-term continuous use of opioids to treat chronic pain was Defendants' collective effort to hide from the medical community the fact that there exist no adequate and well-controlled studies of opioid use longer than 12 weeks.³⁸

³⁷ Research Letter, Prescription Drug Abuse: A National Survey of Primary Care Physicians, JAMA Intern. Med. (Dec. 8, 2014), E1-E3.

³⁸ See note 7.

B. DEFENDANTS USED MULTIPLE AVENUES TO DISSEMINATE THEIR FALSE AND DECEPTIVE STATEMENTS ABOUT OPIOIDS

121. Defendants spread their false and deceptive statements by marketing their branded opioids directly to doctors and patients throughout the country and in this district. Defendants deployed throughout the state seemingly unbiased and independent third parties that they controlled to spread their false and deceptive statements about the risks and benefits of opioids for the treatment of chronic pain.

122. Defendants' direct marketing of Opioids generally proceeded on two tracks. First, each defendant conducted and continue to conduct advertising campaigns touting the purported benefit of their branded drugs. For example, Defendants spent more than \$14 million on medical journal advertising of Opioids in 2011, nearly triple what they spent in 2001. The amount included \$8.3 million by Purdue, \$4.9 million by Janssen, and \$1.1 million by Endo.

123. A number of Defendants' branded ads deceptively portrayed the benefits of Opioids for chronic pain. For example, Endo distributed and made available on its website opana.com, a pamphlet promoting Opana ER with photographs depicting patients with physically demanding jobs like construction worker and chef, misleadingly implying that the drug would provide long-term pain-relief and functional improvement. Purdue also ran a series of ads, called "Pain vignettes," for OxyContin in 2012 in medical journals. These ads featured chronic pain patients and recommended OxyContin for each. One ad described a "54-year-old writer with osteoarthritis of the hands" and implied that OxyContin would help the writer work more effectively. Endo and Purdue agreed in late 2015 and 2016 to halt these misleading representations in New York, but they may continue to disseminate them in Arkansas.

124. Second, each Defendant promoted the use of Opioids for chronic pain through "detailers"- sales representatives who visited individual doctors and medical staff in their offices and small group speaker programs. Defendants have not corrected this misinformation. Instead, each Defendant has devoted and continues to devote massive resources to direct sales contacts

with doctors. In 2014 alone, Defendants spent \$168 million on detailing branded Opioids to doctors. This amount is twice as much as Defendants spent on detailing in 2000. The amount includes \$1.08 million spent by Purdue, \$34 million by Janssen, \$13 million by Cephalon, \$1.0 million by Endo, and \$2 million by Actavis.

125. Defendants' detailers have been reprimanded for their deceptive promotions. A July 2010 "Dear Doctor" letter mandated by the FDA required Actavis to acknowledge to the doctors to whom it marketed its drugs that "[b]etween June 2009 and February 2010, Actavis sales representatives distributed ... promotional materials that ... omitted and minimized serious risks associated with [Kadian]," including the risk of "[m]isuse, [a]buse, and [d]iversion of Opioids" and, specifically, the risk that "Opioid[s] have the potential for being abused and are sought by drug abusers and people with addiction disorders and are subject to criminal diversion."

1. Defendants Trivialized the Risks of Long Term and Higher Dosages Opioid Therapy

126. Discontinuing opioids after more than just a few weeks of therapy will cause most patients to experience withdrawal symptoms. These withdrawal symptoms include: severe anxiety, nausea, vomiting, headaches, agitation, insomnia, tremors, hallucinations, delirium, pain, and other serious symptoms, which may persist for months after a complete withdrawal from opioids, depending on how long the opioids were used.

127. When under the continuous influence of opioids over time, patients grow tolerant to their analgesic effects. As tolerance increases, a patient typically requires progressively higher doses in order to obtain the same levels of pain reduction to which he has become accustomed – up to and including doses that are “frighteningly high.”³⁹ At higher doses, the effects of withdrawal are more substantial, thus leaving a patient at a much higher risk of addiction. A patient can take the opioids at the continuously escalating dosages to match pain tolerance and still overdose at recommended levels.

³⁹ M. Katz, Long-term Opioid Treatment of Nonmalignant Pain: A Believer Loses His Faith, 170(16) Archives of Internal Med. 1422 (2010).

128. Opioids vary by duration. Long-acting opioids, such as Purdue's OxyContin and MS Contin, Janssen's Nucynta ER and Duragesic, Endo's Opana ER, and Actavis's Kadian, are designed to be taken once or twice daily and are purported to provide continuous opioid therapy for, in general, 12 hours. Short-acting opioids, such as Cephalon's Actiq and Fentora, are designed to be taken in addition to long-acting opioids to address "episodic pain" and provide fast-acting, supplemental opioid therapy lasting approximately 4 to 6 hours.

129. Defendants promoted the idea that pain should be treated by taking long-acting opioids continuously and supplementing them by also taking short-acting, rapid-onset opioids for episodic pain.

130. In 2013, in response to a petition to require manufacturers to strengthen warnings on the labels of long-acting opioid products, the FDA warned of the "grave risks" of opioids, including "addiction, overdose, and even death." The FDA further warned, "[e]ven proper use of opioids under medical supervision can result in life-threatening respiratory depression, coma, and death." Because of those grave risks, the FDA said that long-acting or extended release opioids "should be used only when alternative treatments are inadequate."⁴⁰ The FDA required that – going forward – opioid makers of long-acting formulations clearly communicate these risks in their labels.

131. In 2016, the FDA expanded its warnings for immediate-release opioid pain medications, requiring similar changes to the labeling of immediate-release opioid pain medications as it had for extended release opioids in 2013. The FDA also required several additional safety-labeling changes across all prescription opioid products to include additional information on the risk of these medications.⁴¹

132. The facts on which the FDA relied in 2013 and 2016 were well known to

⁴⁰See note 7, *supra*.

⁴¹ FDA announces enhanced warnings for immediate-release opioid pain medications related to risks of misuse, abuse, addiction, overdose and death.
<http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm491739.htm>.

Defendants in the 1990s when their deceptive marketing began.

133. Defendants falsely claimed that doctors and patients could increase Opioid dosages indefinitely without added risk and failed to disclose the greater risks to patients at higher dosages. The ability to escalate dosages was critical to Defendants' efforts to market Opioids for long-term use to treat chronic pain because, absent this misrepresentation, doctors would have abandoned treatment when patients build up tolerance and lower dosages did not provide pain relief. Some illustrative examples are described below:

- a. Actavis' predecessor created a patient brochure for Kadian in 2007 that stated, "Over time, your body may become tolerant of your current dose. You may require a dose adjustment to get the right amount of pain relief. This is not addiction." Upon information and belief, based on Actavis's acquisition of its predecessor's marketing materials along with the rights to Kadian, Actavis continued to use these materials in 2009 and beyond.
- b. Cephalon and Purdue sponsored APF's *Treatment Options a Guide for People Living with Pain* (2007), which claims that some patients "need" a larger dose of an Opioid, regardless of the dose currently prescribed. The guide stated that Opioids have "no ceiling dose" and are therefore the most appropriate treatment for severe pain. This guide is still available for sale online.
- c. Endo sponsored a website, painknowledge.com, which claimed in 2009 that Opioid dosages may be increased until "you are on the right dose of medication for your pain."
- d. Endo distributed a pamphlet edited by a KOL entitled *Understanding Your Pain: Taking Oral Opioid Analgesics*, which was recently available on Endo's website. In Q&A format, it asked "If I take the opioid now, will it work later when I really need it?" The response is, "The dose can be increased You won't 'run out' of pain relief."
- e. Janssen sponsored a patient education guide entitled *Finding Relief Pain Management for Older Adults* (2009), which was distributed by its sales force. This guide listed dosage limitations as "disadvantages" of other pain medicines but omitted any discussion of risks of increased Opioid dosages.
- f. Purdue's In the Face of Pain website promotes the notion that if a patient's doctor does not prescribe what, in the patient's view, is a sufficient dosage or Opioids, he or she should find another doctor who will.
- g. Purdue sponsored APF's *A Policymaker 's Guide to Understanding Pain & Its Management*, which taught that dosage escalations are "sometimes

necessary," even unlimited ones, but did not disclose the risks from high Opioid dosages. This publication is still available online.

- h. Purdue sponsored a CME entitled *Overview of Management Options* that is still available for CME credit. The CME was edited by a KOL and taught that NSAIDs and other drugs, but not Opioids, are unsafe at high dosages.
- i. Purdue presented a 2015 paper at the College on the Problems of Drug Dependence, the "oldest and largest organization in the US dedicated to advancing a scientific approach to substance use and addictive disorders," *see* www.cpdd.org, challenging the correlation between Opioid dosage and overdose.

134. These claims conflict with the scientific evidence, as confirmed by the FDA and CDC. As the CDC explains in its 2016 Guideline, the "[b]enefits of high-dose opioids for chronic pain are not established" while the "risks for serious harms related to opioid therapy increase at higher opioid dosage." More specifically, the CDC explains that "there is now an established body of scientific evidence showing that overdose risk is increased at higher opioid dosages." The CDC also states that "there is an increased risk for opioid use disorder, respiratory depression, and death at higher dosages." That is why the CDC advises doctors to "avoid increasing dosages" above 90 morphine milligram equivalents per day.

135. The 2016 CDC Guideline reinforces earlier findings announced by the FDA. In 2013, the FDA acknowledged "that the available data do suggest a relationship between increasing opioid dose and risk of certain adverse events." For example, the FDA noted that studies "appear to credibly suggest a positive association between high-dose opioid use and the risk of overdose and/or overdose mortality."

136. Defendants' deceptive marketing of the so-called abuse-deterrent properties of some of their Opioids has created false impressions that these Opioids can curb addiction and abuse. Indeed, in a 2014 survey of 1,000 primary care physicians, nearly half reported that they

believed abuse-deterrent formulations are inherently less addictive.⁴²

137. More specifically, Defendants have made misleading claims about the ability of their so-called abuse deterrent Opioid formulations to deter abuse. For example, Endo's advertisement for the 2012 reformulation of Opana ER claimed that it was designed to be crush resistant, in a way that suggested it was more difficult to abuse. This claim was false. The FDA warned in a 2013 letter that there was no evidence Endo's design "would provide a reduction in oral, intranasal, or intravenous abuse." The FDA has subsequently taken the extraordinary action of "request[ing] that Endo Pharmaceuticals remove ... Opana ER ... from the market."⁴³

138. According to the FDA, Endo's reformulation of Opana ER "made things worse": "[P]ostmarketing data ... demonstrate[s] a significant shift in the route of abuse of Opana ER from nasal to injection following the product's reformulation." Moreover, Endo's own studies, which it fails to disclose, showed that Opana ER could still be ground and chewed.

139. In a 2016 settlement with the State of New York, Endo agreed not to make statements in New York that Opana ER was "designed to be, or is crush resistant." The State found these statements false and deceptive because there was no difference in the ability to extract the narcotic from Opana ER. Similarly, the 2016 CDC Guideline states that "[n]o studies" support the notion that "abuse-deterrent technologies [are] a risk mitigation strategy for deterring or preventing abuse," noting that the technologies - even when they work - "do not prevent opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by non-oral routes."

140. These numerous, longstanding misrepresentations of the risks of long-term opioid

⁴² Catherine S. Hwang et al., Prescription Drug Abuse: A National Survey of Primary Care Physicians, 75(2) JAMA Intern. Med. 302-04 (Dec. 8, 2014)

⁴³ Maggie Fox, *FDA Asks Drug Company to Pull its Opioid Opana Because of Abuse*, NBCNews.com (June 9, 2017), <http://www.nbcnews.com/story line/americas-heroin-epidemic/fda-asks-drug-companypull-its-opioid-opana-because-abuse-n770121>

use spread by Defendants successfully convinced doctors and patients to discount those risks.

141. Defendants also identified doctors to serve, for payment, on their speakers' bureaus and to attend programs with speakers and meals paid for by Defendants. These speaker programs provided: (1) an incentive for doctors to prescribe a particular Opioid (so they might be selected to promote the drug); (2) recognition and compensation for the doctors selected as speakers; and (3) an opportunity to promote the drug through the speaker to his or her peers. These speakers give the false impression that they are providing unbiased and medically accurate presentations when they are, in fact, presenting a script prepared by Defendants. On information and belief, these presentations conveyed misleading information, omitted material information, and failed to connect Defendants' prior misrepresentations about the risks and benefits of Opioids.

142. Defendants' detailing to doctors is effective. Numerous studies indicate that marketing impacts prescribing habits, with face-to-face detailing having the greatest influence. Even without such studies, Defendants purchase, manipulate, and analyze some of the most sophisticated data available in *any* industry, data available from IMS Health Holdings, Inc., to track, precisely, the rates of initial prescribing and renewal by individual doctor, which in turn allows them to target, tailor, and monitor the impact of their core messages. Thus, Defendants *know* their detailing to doctors is effective.

143. To convince doctors and patients that Opioids are safe, Defendants deceptively trivialized and failed to disclose the risks of long-term Opioid use, particularly the risk of addiction, through a series of misrepresentations that have been conclusively debunked by the FDA and CDC. These misrepresentations - which are described below - reinforced each other and created the dangerously misleading impression that: (1) starting patients on Opioids was low-risk because most patients would not become addicted, and because those who were at greatest risk of addiction could be readily identified and managed; (2) patients who displayed signs of addiction probably

were not addicted and, in any event, could be easily weaned from the drugs; (3) the use of higher Opioid doses, which many patients need to sustain pain relief as they develop tolerance to the drugs, do not pose special risks; and (4) abuse-deterrent Opioids both prevent abuse and overdose and are inherently less addictive. Defendants have not only failed to correct these misrepresentations, they continue to make them today.

144. Defendants falsely claimed that the risk of addiction is low and that addiction is unlikely to develop when Opioids are prescribed, as opposed to obtained illicitly; and failed to disclose the greater risk of addiction with prolonged use of Opioids. Some illustrative examples of these false and deceptive claims are described below:

- a. Actavis's predecessor caused a patient education brochure to be distributed in 2007 that claimed Opioid addiction is possible, but "less likely if you have never had an addiction problem." Upon information and belief, based on Actavis' acquisition of its predecessor's marketing materials along with the rights to Kadian, Actavis continued to use this brochure in 2009 and beyond.
- b. Cephalon and Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which instructed that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining duplicative Opioid prescriptions from multiple sources, or theft. This publication is still available online.
- c. Endo sponsored a website, Painknowledge.com, which claimed in 2009 that "[p]eople who take opioids as prescribed usually do not become addicted." Another Endo website, PainAction.com, stated "Did you know? Most chronic pain patients do not become addicted to the Opioid medications that are prescribed for them."
- d. Endo distributed a pamphlet with the Endo logo entitled *Living with Someone with Chronic Pain*, which stated that: "Most health care providers who treat people with pain agree that most people do not develop an addiction problem." A similar statement appeared on the Endo website.
- e. Janssen reviewed, edited, approved, and distributed a patient education guide entitled *Finding Relief Pain Management for Older Adults* (2009), which described as "myth" the claim that Opioids are addictive, and asserted as fact that "[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain."

- f. Janssen currently runs a website, Prescriberesponsibly.com (last updated July 2, 2015), which claims that concerns about Opioid addiction are "overestimated."
- g. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management* - which claims that less than 1% of children prescribed Opioids will become addicted and that pain is undertreated due to "misconceptions about opioid addiction[]." This publication is still available Online.
- h. Detailers for Purdue/Abbott, Endo, Janssen, and Cephalon throughout the country and in the state of New York and in this district omitted any discussion with doctors of the risk of addiction; misrepresented the potential for abuse of Opioids with purportedly abuse deterrent formulations; and routinely did not correct the misrepresentations noted above.

145. These claims are contrary to longstanding scientific evidence, as the FDA and CDC have conclusively declared. As noted in the 2016 CDC Guideline endorsed by the FDA, there is "extensive evidence" of the "possible harms of Opioids (including opioid use disorder [an alternative term for Opioid addiction])." The Guideline points out that "Opioid pain medication use presents serious risks, including ... opioid use disorder" and that "continuing opioid therapy for 3 months substantially increases the risk for opioid use disorder."

146. The FDA further exposed the falsity of Defendants' claims about the low risk of addiction when it announced changes to the labels for ER/LA Opioids in 2013 and for IR Opioids in 2016. In its announcements, the FDA found that "most opioid drugs have 'high potential for abuse'" and that Opioids "are associated with a substantial risk of misuse, abuse, NOWS [neonatal Opioid withdrawal syndrome], addiction, overdose, and death." According to the FDA, because of the "known serious risks" associated with long-term Opioid use, including "risks of addiction, abuse, and misuse, even at recommended doses, and because of the greater risks of overdose and death," Opioids should be used only "in patients for whom alternative treatment options" like non-Opioid drugs have failed. The FDA further acknowledged that the risk is not limited to patients

who seek drugs illicitly; addiction "can occur in patients appropriately prescribed [Opioids]."

147. The warnings on Defendants' own FDA-approved drug labels caution that Opioids "expose[] users to risks of addiction, abuse and misuse, which can lead to overdose and death," that the drugs contain "a substance with a high potential for abuse," and that addiction "can occur in patients appropriately prescribed" Opioids.

148. The State of New York, in a 2016 settlement agreement with Endo, found that Opioid "use disorders appear to be highly prevalent in chronic pain patients treated with opioids, with up to 40% of chronic pain patients treated in specialty and primary care outpatient centers meeting the clinical criteria for an opioid use disorder." Endo had claimed on its www.opana.com website that "[m]ost healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted," but the State found that Endo had no evidence for that statement.⁴⁴ Consistent with this, Endo agreed not to "make statements that ... opioids are generally non-addictive" or "that most patients who take opioids do not become addicted" in New York. Endo remains free, however, to make those statements in other states including New York.

149. Defendants falsely instructed doctors and patients that the signs of addiction are actually signs of undertreated pain and should be treated by prescribing more Opioids. Defendants have called this phenomenon "pseudoaddiction"- a term coined by Dr. David Haddox, who went to work for Purdue, and popularized by Dr. Russell Portenoy, a KOL for Cephalon, Endo, Janssen, and Purdue - and falsely claimed that pseudoaddiction is substantiated by scientific evidence. Some illustrative examples of theses deceptive claims are described below:

- a. Cephalon and Purdue sponsored *Responsible Opioid Prescribing* (2007), which taught that behaviors such as "requesting drugs by name,"

⁴⁴ See *Endo Health Solutions Inc.*, Assurance of Discontinuance, at 6 (N.Y. Att. Gen. Mar. 1, 2016).

"demanding or manipulative behavior," seeing more than one doctor to obtain Opioids, and hoarding, are all signs of pseudoaddiction, rather than true addiction. *Responsible Opioid Prescribing* remains for sale online. The 2012 edition, which also remains available online, continues to falsely teach that pseudoaddiction is real.

- b. Janssen sponsored, funded, and edited the *Let's Talk Pain* website, which in 2009 stated: "[P]seudoaddiction ... refers to patient behaviors that may occur when pain is undertreated Pseudoaddiction is different from true addiction because such behaviors can be resolved with effective pain management."
- c. Endo sponsored a National Initiative on Pain Control (NIPC) CME program in 2009 titled *Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia*, which promoted pseudoaddiction by teaching that a patient's aberrant behavior was the result of untreated pain. Endo substantially controlled NIPC by funding NIPC projects; developing, specifying, and reviewing content; and distributing NIPC materials.
- d. Purdue published a pamphlet in 2011 entitled *Providing Relief, Preventing Abuse*, which described pseudoaddiction as a concept that "emerged in the literature" to describe the inaccurate interpretation of "[drug-seeking behaviors] in patients who have pain that has not been effectively treated."
- e. Purdue sponsored a CME program entitled *Path of the Patient, Managing Chronic Pain in Younger Adults at Risk for Abuse*. In a role play, a chronic pain patient with a history of drug abuse tells his doctor that he is taking twice as many hydrocodone pills as directed. The narrator notes that because of pseudoaddiction, the doctor should not assume the patient is addicted even if he persistently asks for a specific drug, seems desperate, hoards medicine, or "overindulges in unapproved escalating doses." The doctor treats this patient by prescribing a high-dose, long-acting Opioid.

150. The 2016 CDC Guideline rejects the concept of pseudoaddiction. The Guideline nowhere recommends that Opioid dosages be increased if a patient is not experiencing pain relief. To the contrary, the Guideline explains that "[p]atients who do not experience clinically meaningful pain relief early in treatment ... are unlikely to experience pain relief with longer term use," and that physicians should "reassess[] pain and function within 1 month" in order to decide whether to "minimize the risks of long-term opioid use by discontinuing opioids" because the

patient is "not receiving a clear benefit."

151. Defendants employed the same marketing plans and strategies and deployed the same message in New York as they did nationwide. Across the pharmaceutical industry, "core message" development is funded and overseen on a national basis by corporate headquarters. This comprehensive approach ensures that Defendants' messages are accurately and consistently delivered across marketing channels - including detailing visits, speaker events, and advertising - and in each sales territory. Defendants consider this high level of coordination and uniformity crucial to successfully marketing their drugs.

152. Defendants ensure marketing consistency nationwide through national and regional sales representative training; national training of local medical liaisons, the company employees who respond to physician inquiries; centralized speaker training; single sets of visual aids, speaker slide decks, and sales training materials; and nationally coordinated advertising. Defendants' sales representatives and physician speakers were required to stick to prescribed talking points, sales messages, and slide decks, and supervisors rode along with them periodically to check on both their performance and compliance.

2. Defendants used a diverse group of seemingly independent third parties to spread false and deceptive statements about the risks and benefits of Opioids

153. Defendants also deceptively marketed Opioids through unbranded advertising - *i.e.*, advertising that promotes Opioid use generally but does not name a specific Opioid. This advertising was ostensibly created and disseminated by independent third-parties. But by funding, directing, reviewing, editing, and distributing this unbranded advertising, Defendants controlled the deceptive messages disseminated by these third parties and acted in concert with them to falsely and misleadingly promote Opioids for the treatment of chronic pain. Much as Defendants controlled the distribution of their "core messages" via their own detailers and speaker programs, Defendants similarly controlled the distribution of these messages in scientific publications,

treatment guidelines, CMEs, and medical conferences and seminars. To this end, Defendants used third-party public relations firms to help control those messages when they originated from third-parties.

154. Defendants also marketed through third-party, unbranded advertising to avoid regulatory scrutiny because that advertising is not submitted to and typically is not reviewed by the FDA. Defendants also used third-party, unbranded advertising to give the false appearance that the deceptive messages came from an independent and objective source. Like cigarette makers, which engaged in an industry-wide effort to misrepresent the safety and risks of smoking, Defendants worked with each other and with the Front Groups and KOLs they funded and directed to carry out a common scheme to deceptively market opioids by misrepresenting the risks, benefits, and superiority of opioids to treat chronic pain. Defendants acted through and with the same network of Front Groups, funded the same KOLs, and often used the very same language and format to disseminate the same deceptive messages regarding the appropriate use of opioids to treat chronic pain. Although participants knew this information was false and misleading, these misstatements were nevertheless disseminated nationwide, including prescribers and patients in this district.

155. Defendants' deceptive unbranded marketing often contradicted what they said in their branded materials reviewed by the FDA. For example, Endo's unbranded advertising contradicted its concurrent, branded advertising for Opana ER:

Pain: Opioid Therapy (Unbranded)	Opana ER Advertisement (Branded)
"People who take opioids as prescribed usually do not become addicted."	"All patients treated with opioids require careful monitoring for signs of abuse and addiction, since use of opioid analgesic products carries the risk of addiction even under appropriate medical use."

a. Key Opinion Leaders ("KOLs")

156. Defendants also spoke through a small circle of doctors who, upon information and belief, were selected, funded, and elevated by Defendants because their public positions supported the use of Opioids to treat chronic pain. These doctors became known as "key opinion leaders" or "KOLs."

157. Defendants paid KOLs to serve as consultants on their advisory boards and to give talks or present CMEs, and their support helped these KOLs become respected industry experts. As they rose to prominence, these KOLs touted the benefits of Opioids to treat chronic pain, repaying Defendants by advancing their marketing goals. KOLs' professional reputations became dependent on continuing to promote a pro-Opioid message, even in activities that were not directly funded by Defendants.

158. KOLs have written, consulted on, edited, and lent their names to books and articles, and given speeches and CMEs supportive of chronic Opioid therapy. Defendants have created opportunities for KOLs to participate in research studies Defendants suggested or chose and then cited and promoted favorable studies or articles by their KOLs. By contrast, Defendants did not support, acknowledge, or disseminate publications of doctors unsupportive or critical of chronic Opioid therapy.

159. Defendants' KOLs also served on committees that developed treatment guidelines that strongly encourage the use of Opioids to treat chronic pain, and on the boards of pro-Opioid advocacy groups and professional societies that develop, select, and present CMEs. Defendants were able to direct and exercise control over each of these activities through their KOLs. The 2016 CDC Guideline recognizes that treatment guidelines can "change prescribing practices."

160. Pro-Opioid doctors are one of the most important avenues that Defendants use to spread their false and deceptive statements about the risks and benefits of long-term Opioid use.

Defendants knew that doctors rely heavily and less critically on their peers for guidance, and KOLs provide the false appearance of unbiased and reliable support for chronic Opioid therapy. For example, the State of New York found in its settlement with Purdue that the Purdue website *In the Face of Pain* failed to disclose that doctors who provided testimonials on the site were paid by Purdue and concluded that Purdue's failure to disclose these financial connections potentially misled consumers regarding the objectivity of the testimonials.⁴⁵

161. Thus, even though some of the KOLs have recently moderated or conceded the lack of evidence for many of the claims they made, these admissions did not reverse the effect of the false and deceptive statements that continue to appear nationwide and throughout the State of New York in Defendants' own marketing as well as treatment guidelines, CMEs and other seminars, scientific articles and research, and other publications available in paper or online.

162. Defendants utilized many KOLs, including many of the same ones. Two of the most prominent are described below.

(1) Russell Portenoy

163. Dr. Russell Portenoy, former chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York, is one example of a KOL whom Defendants identified and promoted to further their marketing campaign. Dr. Portenoy received research support, consulting fees, and honoraria from Cephalon, Endo, Janssen, and Purdue (among others), and was a paid consultant to Cephalon and the Purdue/Abbott cabal.

164. In 1986, Dr. Russell Portenoy published an article reporting that “[f]ew substantial gains in employment or social function could be attributed to the institution of opioid

⁴⁵ See *In re Purdue Pharma L.P.*, Assurance of Discontinuance, 18, at 8 (N.Y. Att. Gen. Aug. 19, 2015) (“[T]he website failed to disclose that from 2008 to 2013, Purdue made payments totaling almost \$231,000, for speaker programs, advisory meetings, and travel costs, to II of the Advocates whose testimonials appeared on the site.”).

therapy.”⁴⁶

165. Writing in 1994, Dr. Portenoy described the prevailing attitudes regarding the dangers of long-term use of opioids:

*The traditional approach to chronic non-malignant pain does not accept the long- term administration of opioid drugs. This perspective has been justified by the perceived likelihood of tolerance, which would attenuate any beneficial effects over time, and the potential for side effects, worsening disability, and addiction. According to conventional thinking, the initial response to an opioid drug may appear favorable, with partial analgesia and salutary mood changes, but adverse effects inevitably occur thereafter. It is assumed that the motivation to improve function will cease as mental clouding occurs and the belief takes hold that the drug can, by itself, return the patient to a normal life. Serious management problems are anticipated, including difficulty in discontinuing a problematic therapy and the development of drug seeking behavior induced by the desire to maintain analgesic effects, avoid withdrawal, and perpetuate reinforcing psychic effects. There is an implicit assumption that little separates these outcomes from the highly aberrant behaviors associated with addiction.*⁴⁷

According to Dr. Portenoy, the foregoing problems could constitute “compelling reasons to reject long-term opioid administration as a therapeutic strategy in all but the most desperate cases of chronic nonmalignant pain.”⁴⁸

166. For all the reasons outlined by Dr. Portenoy, and in the words of one researcher from the University of Washington in 2012, and quoted by a Harvard researcher the same year, “it did not enter [doctors’] minds that there could be a significant number of chronic pain patients who were successfully managed with opioids, because if there were any, we almost never saw them.”⁴⁹

⁴⁶ R. Portenoy & K. Foley, Chronic Use of Opioid Analgesics in Non-Malignant Pain: Report of 38 cases, 25(2) Pain 171 (1986).

⁴⁷ R. Portenoy, *Opioid Therapy for Chronic Nonmalignant Pain: Current Status*, 1 Progress in Pain Res. & Mgmt., 247-287 (H.L. Fields and J.C. Liebeskind eds., 1994) (emphasis added).

⁴⁸ *Id.*

⁴⁹ J. Loeser. Five crises in pain management, Pain Clinical Updates. 2012;20 (1):1–4(cited by I. Kissin, Long-term opioid treatment of chronic nonmalignant pain: unproven efficacy and neglected safety?, 6 J. Pain Research 513, 514 (2013)).

167. Despite his writings in 1994, Dr. Portenoy was instrumental in opening the door for regular use of Opioids to treat chronic pain. He served on the American Pain Society ("APS") American Academy of Pain Medicine ("AAPM") Guideline Committees, which endorsed the use of Opioids to treat chronic pain, first in 1997 and again in 2009. He was also a member of the board of the American Pain Foundation ("APF"), an advocacy organization almost entirely funded by Defendants.

168. Dr. Portenoy also made frequent media appearances promoting Opioids and spreading misrepresentations. He appeared on *Good Morning America* in 2010 to discuss the use of Opioids long-term to treat chronic pain. On this widely-watched program, broadcast in New York and across the country, Dr. Portenoy claimed: "Addiction, when treating pain, is distinctly uncommon. If a person does not have a history, a personal history, of substance abuse, and does not have a history in the family of substance abuse, and does not have a very major psychiatric disorder, most doctors can feel very assured that that person is not going to become addicted."⁵⁰

169. To his credit, Dr. Portenoy later admitted that he "gave innumerable lectures in the late 1980s and '90s about addiction that weren't true." These lectures falsely claimed that fewer than 1% of patients would become addicted to Opioids. According to Dr. Portenoy, because the primary goal was to "destigmatize" Opioids, he and other doctors promoting them overstated their benefits and glossed over their risks. Dr. Portenoy also conceded that "[d]ata about the effectiveness of Opioids does not exist."⁵¹ Portenoy candidly stated: "Did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? Well, ... I guess I did."⁵²

⁵⁰ *Good Morning America Television Broadcast*, ABC News (Aug. 30, 2010).

⁵¹ Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, Wall St. J., Dec. 17, 2012.

⁵² *Id.*

(2) Lynn Webster

170. Another KOL, Dr. Lynn Webster, was the co-founder and Chief Medical Director of Lifetree Clinical Research, an otherwise unknown pain clinic in Salt Lake City, Utah. Dr. Webster was president in 2013 and is a current board member of AAPM, a front group that ardently supports chronic Opioid therapy. He is Senior Editor of *Pain Medicine*, the same journal that published Endo special advertising supplements touting Opana ER. Dr. Webster was the of numerous CMEs sponsored by Cephalon, Endo, and Purdue. At the same time, Dr. Webster was receiving significant funding from Defendants (including nearly \$2 million from Cephalon).

171. During a portion of his time as a KOL, Dr. Webster was under investigation for overprescribing by the U.S. Department of Justice's Drug Enforcement Agency, which raided his clinic in 2010. Although the investigation was closed without charges in 2014, more than 20 of Dr. Webster's former patients at the Lifetree Clinic have died of Opioid overdoses.

172. Dr. Webster created and promoted the Opioid Risk Tool, a five question, one-minute screening tool relying on patient self-reports that purportedly allows doctors to manage the risk that their patients will become addicted to or abuse Opioids. The claimed ability to pre-sort patients likely to become addicted is an important tool in giving doctors confidence to prescribe Opioids long-term, and for this reason, references to screening appear in various industry supported guidelines. Versions of Dr. Webster's Opioid Risk Tool appear on, or are linked to, websites run by Endo, Janssen, and Purdue.

173. In 2011, Dr. Webster presented, via webinar, a program sponsored by Purdue titled, *Managing Patients' Opioid Use: Balancing the Need and the Risk*. Dr. Webster recommended use of risk screening tools, urine testing, and patient agreements as a way to prevent "overuse of

prescriptions" and "overdose deaths." This webinar was available to and was intended to reach doctors across the country including in New York.

174. Dr. Webster also was a leading proponent of the concept of "pseudoaddiction," the notion that addictive behaviors should not be seen as warnings, but as indications of undertreated pain. In Dr. Webster's description, the only way to differentiate the two was to *increase* a patient's dose of Opioids. As he and his co-author wrote in a book entitled *Avoiding Opioid Abuse While Managing Pain* (2007), a book that is still available online, when faced with signs of aberrant behavior, increasing the dose "in most cases ... should be the clinician's first response." Endo distributed this book to doctors. Years later, Dr. Webster reversed himself, acknowledging that "[pseudoaddiction] obviously became too much of an excuse to give patients more medication."⁵³

b. Front Groups

175. Defendants also entered into arrangements with seemingly unbiased and independent patient and professional organizations to promote Opioids for the treatment of chronic pain. Under the direction and control of Defendants, these "Front Groups" generated treatment guidelines, unbranded materials, and programs that favored chronic Opioid therapy. They also assisted Defendants by responding to negative articles, by advocating against regulatory changes that would limit Opioid prescribing in accordance with the scientific evidence, and by conducting outreach to vulnerable patient populations targeted by Defendants.

176. These Front Groups depended on Defendants for funding and, in some cases, for survival. Defendants also exercised control over programs and materials created by these groups by collaborating on, editing, and approving their content, and by funding their dissemination. In doing so, Defendants made sure that the Groups would generate only the messages Defendants

⁵³John Fauber, *Networking Fuels Painkiller Boom*, Bangor Daily News.

wanted to distribute. Despite this, the Front Groups held themselves out as independent and serving the needs of their members -whether patients suffering from pain or doctors treating those patients.

177. Defendants Cephalon, Endo, Janssen, and Purdue utilized many Front Groups, including many of the same ones. Several of the most prominent are described below, but there are many others, including the American Pain Society ("APS"), American Geriatrics Society ("AGS"), the Federation of State Medical Boards ("FSMB"), American Chronic Pain Association ("ACPA"), American Society of Pain Education ("ASPE"), National Pain Foundation ("NPF"), and Pain & Policy Studies Group ("PPSG").

(1) American Pain Foundation ("APF")

178. The most prominent of Defendants' Front Groups was APF, which received more than \$10 million in funding from Opioid manufacturers from 2007 until it closed its doors in May 2012. Endo alone provided more than half that funding; Purdue was next, at \$1.7 million.

179. APF issued education guides for patients, reporters, and policymakers that touted the benefits of Opioids for chronic pain and trivialized their risks, particularly the risk of addiction. APF also launched a campaign to promote Opioids for returning veterans, which has contributed to high rates of addiction and other adverse outcomes- including death- among returning soldiers. APF also engaged in a significant multimedia campaign - through radio, television, and the internet - to educate patients about their "right" to pain treatment, namely Opioids. All of the programs and materials were available nationally and were intended to reach New York consumers, physicians, patients, and TPP's.

180. In addition to Perry Fine (a KOL from the University of Utah who received funding from Janssen, Cephalon, Endo, and Purdue), Russell Portenoy, and Scott Fishman (a KOL from the University of California, Davis who authored *Responsible Opioid Prescribing*, a publication sponsored by Cephalon and Purdue), all of whom served on APF's board and reviewed its publications, another board member, Lisa Weiss, was an employee of a public relations firm that worked for both Purdue and APF.

181. In 2009 and 2010, more than 80% of APF's operating budget came from pharmaceutical industry sources. Including industry grants for specific projects, APF received about \$2.3 million from industry sources out of total income of about \$2.85 million in 2009; its budget for 2010 projected receipts of roughly \$2.9 million from drug companies, out of total income of about \$3.5 million. By 2011, APF was entirely dependent on incoming grants from defendants Purdue, Cephal on, Endo, and others to avoid using its line of credit. As one of its board members, Russell Portenoy, explained, the lack of funding diversity was one of the biggest problems at APF.

182. APF held itself out as an independent patient advocacy organization. It often engaged in grassroots lobbying against various legislative initiatives that might limit Opioid prescribing, and thus the profitability of its sponsors. It was often called upon to provide "patient representatives" for Defendants' promotional activities, including for Purdue's *Partners Against Pain* and Janssen's *Let's Talk Pain*. APF functioned largely as an advocate for the interests of Defendants, not patients. Indeed, as early as 2011, Purdue told APF that the basis of a grant was Purdue's desire to "strategically align its investments in nonprofit organizations that share [its] business interests."

183. In practice, APF operated in close collaboration with Opioid makers. On several occasions, representatives of the drug companies, often at informal meetings at Front Group conferences, suggested activities and publications for APF to pursue. APF then submitted grant proposals seeking to fund those activities and publications, knowing that drug companies would support projects conceived as a result of those communications.

184. APF assisted in other marketing projects for drug companies. One project funded by another drug company-*AP F Reporter's Guide: Covering Pain and Its Management* (2009) recycled text that was originally created as part of the company's training document.

185. The same drug company made general grants, but even then, it directed how APF used them. In response to an APF request for funding to address a potentially damaging state Medicaid decision related to pain medication generally, the company representative responded, "I

provided an advocacy grant to APF this year - this would be a very good issue on which to use some of that. How does that work?"

186. The close relationship between APF and the drug company highlighted in the previous paragraph was not unique, but mirrors relationships between APF and Defendants. APF's clear lack of independence - in its finances, management, and mission - and its willingness to allow Defendants to control its activities and messages support an inference that each Defendant that worked with it was able to exercise editorial control over its publications.

187. Indeed the U.S. Senate Finance Committee began looking into APF in May 2012 to determine the links, financial and otherwise, between the organization and the manufacturers of Opioid painkillers. The investigation caused considerable damage to APF's credibility as an objective and neutral third party, and Defendants stopped funding it. Within days of being targeted by Senate investigation, APF's board voted to dissolve the organization "due to irreparable economic circumstances." APF "cease[d] to exist, effective immediately."

(2) American Academy of Pain Medicine ("AAPM")

188. The American Academy of Pain Medicine, with the assistance, prompting, involvement, and funding of Defendants, issued treatment guidelines and sponsored and hosted medical education programs essential to Defendants' deceptive marketing of chronic Opioid therapy.

189. AAPM received over \$2.2 million in funding since 2009 from Opioid manufacturers. AAPM maintained a corporate relations council, whose members paid \$25,000 per year (on top of other funding) to participate. The benefits included allowing members to present educational programs at off-site dinner symposia in connection with AAPM's marquee event - its annual meeting held in Palm Springs, California, or other resort locations. AAPM described the annual event as an "exclusive venue" for offering education programs to doctors. Membership in the corporate relations council also allows drug company executives and marketing staff to meet with AAPM executive committee members in small settings. Defendants Endo, Purdue, Cephalon, and Actavis were members of the council and presented deceptive programs to doctors who

attended this annual event.

190. AAPM is viewed internally by Endo as "industry friendly," with Endo advisors and speakers among its active members. Endo attended AAPM conferences, funded its CMEs, and distributed its publications. The conferences sponsored by AAPM heavily emphasized sessions on Opioids- 37 out of roughly 40 at one conference alone. AAPM's presidents have included top industry-supported KOLs Perry Fine, Russell Portenoy, and Lynn Webster. Another past AAPM president, Dr. Scott Fishman, stated that he would place the organization "at the forefront" of teaching that "the risks of addiction are ... small and can be managed."⁵⁴

191. AAPM's staff understood they and their industry funders were engaged in a common task. Defendants were able to influence AAPM through both their significant and regular funding and the leadership of pro-Opioid KOLs within the organization.

192. In addition, treatment guidelines have been particularly important in securing acceptance for chronic Opioid therapy. They are relied upon by doctors, especially the general practitioners and family doctors targeted by Defendants, who are neither experts nor trained in the treatment of chronic pain. Treatment guidelines not only directly inform doctors' prescribing practices, but are cited throughout the scientific literature and referenced by third-party payors in determining whether they should cover treatments for specific indications. Pharmaceutical sales representatives employed by Endo, Actavis, and Purdue discussed treatment guidelines with doctors during individual sales visits.

193. In 1997, AAPM and the American Pain Society jointly issues a consensus statement, *The Use of Opioids for the Treatment of Chronic Pain*, which endorsed Opioids to treat chronic pain and claimed that the risk that patients would become addicted to Opioids was low. The co-author of the statement, Dr. Haddox, was at the time a paid speaker for Purdue. Dr. Portenoy was the sole consultant. The consensus statement remained on AAPM's website until

⁵⁴ Interview by Paula Moyer with Scott M. Fishman, M.D., Professor of Anesthesiology and Pain Medicine, Chief of the Division of Pain Medicine, Univ. of Cal., Davis (2005), available at <http://www.medscape.org/viewarticle/500829>.

2011, and was taken down from AAPM's website only after a doctor complained, though it lingers on the internet elsewhere.

194. AAPM and APS issued their own guidelines in 2009 ("AAPM/APS Guidelines") and continued to recommend the use of Opioids to treat chronic pain. Fourteen of the 21 panel members who drafted the AAPM/APS Guidelines, including KOLs Dr. Portenoy and Dr. Perry Fine of the University of Utah, received support from Janssen, Caphalon, Endo, and Purdue.

195. The 2009 Guidelines promote Opioids as "safe and effective" for treating chronic pain, despite acknowledging limited evidence, and conclude that the risk of addiction is manageable for patients regardless of past abuse histories. One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache and Neurological Institute, resigned from the panel because of his concerns that the 2009 Guidelines were influenced by contributions that drug companies, including Defendants, made to the sponsoring organizations and committee members. These AAPM/APS Guidelines have been a particularly effective channel of deception and have influenced not only treating physicians, but also the body of scientific evidence on Opioids; the Guidelines have been cited 732 times in academic literature, were disseminated in nationwide and in New York during the relevant time period, are still available online, and were reprinted in the *Journal of Pain*.

196. Defendants widely referenced and promoted the 2009 Guidelines without disclosing the acknowledged lack of evidence to support them.

197. Defendants worked together, through Front Groups, to spread their deceptive messages about the risks and benefits of long-term Opioid therapy. For example, Defendants combined their efforts through the Pain Care Forum ("PCF"), which began in 2004 as an APF project with the stated goals of offering "a setting where multiple organizations can share information" and "promote and support taking collaborative action regarding federal pain policy issues." APF President Will Rowe described the forum as "a deliberate effort to positively merge the capacities of industry, professional associations, and patient organizations."

198. PCF is comprised of representatives from opioid manufacturers and distributors

(including Cephalon, Endo, Janssen, and Purdue); doctors and nurses in the field of pain care; professional organizations (including AAPM, APS, and American Society of Pain Educators); patient advocacy groups (including APF and American Chronic Pain Association ("ACPA")); and other like-minded organizations, almost all of which received substantial funding from Defendants.

199. PCF, for example, developed and disseminated "consensus recommendations" for a Risk Evaluation and Mitigation Strategy ("REMS") for long-acting opioids that the FDA mandated in 2009 to communicate the risks of opioids to prescribers and patients.⁵⁵ This was critical because a REMS that went too far in narrowing the uses or benefits or highlighting the risks of chronic opioid therapy would undermine Defendants' marketing efforts. The recommendations claimed that opioids were "essential" to the management of pain, and that the REMS "should acknowledge the importance of opioids in the management of pain and should not introduce new barriers." Defendants worked with PCF members to limit the reach and manage the message of the REMS, which enabled them to maintain, not undermine, their deceptive marketing of opioids for chronic pain.

C. OPIOID THERAPY MAKES PATIENTS SICKER WITHOUT LONG TERM BENEFITS

200. There is no scientific evidence supporting the safety or efficacy of opioids for long-term use. Defendants are well aware of the lack of such scientific evidence. While promoting opioids to treat chronic pain, Defendants failed to disclose the lack of evidence to support their use long-term and have failed to disclose the substantial scientific evidence that chronic opioid therapy actually makes patients sicker.

201. There are no controlled studies of the use of opioids beyond 16 weeks, and no evidence that opioids improve patients' pain and function long-term. For example, a 2007 systematic review of opioids for back pain concluded that opioids have limited, if any, efficacy

⁵⁵ The FDA can require a drug maker to develop a REMS—which could entail (as in this case) an education requirement or distribution limitation—to manage serious risks associated with a drug.

for back pain and that evidence did not allow judgments regarding long- term use.

202. Substantial evidence exists that opioid drugs are ineffective to treat chronic pain, and actually worsen patients' health. For example, a 2006 study-of-studies found that opioids as a class did not demonstrate improvement in functional outcomes over other non-addicting treatments.⁵⁶

203. Increasing duration of opioid use is strongly associated with an increasing prevalence of mental health conditions (including depression, anxiety, post-traumatic stress disorder, or substance abuse), increased psychological distress, and greater health care utilization.

204. While opioids may work acceptably well for a while, when they are used on a long-term basis, function generally declines, as does general health, mental health, and social function. Over time, even high doses of potent opioids often fail to control pain, and patients exposed to such doses are unable to function normally.⁵⁷

205. The foregoing is true both generally and for specific pain-related conditions. Studies of the use of opioids long-term for chronic lower back pain have been unable to demonstrate an improvement in patients' function. Instead, research consistently shows that long-term opioid therapy for patients who have lower back injuries does not cause patients to return to work or physical activity. This is due partly to addiction and other side effects.

206. For example, as many as 30% of patients who suffer from migraines have been prescribed opioids to treat their headaches. Users of opioids had the highest increase in the number of headache days per month, scored significantly higher on the Migraine Disability Assessment, and had higher rates of depression, compared to non-opioid users. A survey by the National

⁵⁶ A. Furlan *et al.*, *Opioids for chronic noncancer pain: a meta-analysis of effectiveness and side effects*, 174(11) Can. Med. Ass'n J. 1589 (2006). This same study revealed that efficacy studies do not typically include data on opioid addiction. In many cases, patients who may be more prone to addiction are pre-screened out of the study pool. This does not reflect how doctors actually prescribe the drugs, because even patients who have past or active substance use disorders tend to receive higher doses of opioids. K. Seal, *Association of Mental Health Disorders With Prescription Opioids and High- Risk Opioids in US Veterans of Iraq and Afghanistan*, 307(9) J. Am. Med. Ass'n 940 (2012).

⁵⁷ See A. Rubenstein, *Are we making pain patients worse?* Sonoma Medicine (Fall 2009).

Headache Foundation found that migraine patients who used opioids were more likely to experience sleepiness, confusion, and rebound headaches, and reported a lower quality of life than patients taking other medications.

D. DEFENDANTS' SCHEME TO CHANGE PRESCRIBER HABITS AND PUBLIC PERCEPTION

207. Before Defendants began the marketing campaign complained of herein, generally accepted standards of medical practice dictated that opioids should only be used short-term, for instance, for acute pain, pain relating to recovery from surgery, or for cancer or palliative care. In those instances, the risks of addiction are low or of little significance.

208. The market for short-term pain relief is significantly more limited than the market for long-term chronic pain relief. Defendants recognized that if they could sell opioids not just for short term pain relief but also for long-term chronic pain relief, they could achieve blockbuster levels of sales and their profits. Further, they recognized that if they could cause their customers to become physically addicted to their drugs, they would increase the likelihood that their blockbuster profits would continue indefinitely.

209. Defendants knew that in order to increase their profits from the sale of opioids they would need to convince doctors and patients that long-term opioid therapy was safe and effective. Defendants needed, in other words, to persuade physicians to abandon their long-held apprehensions about prescribing opioids, and instead to prescribe opioids for durations previously understood to be unsafe.

210. Defendants knew that their goal of increasing profits by promoting the prescription of opioids for chronic pain would lead directly to an increase in health care costs for patients, health care insurers, and health care payors such as Plaintiff.

211. Marshalling help from consultants and public relations firms, Defendants developed and executed a common strategy to reverse the long-settled understanding of the relative risks and benefits of chronic opioid therapy. Rather than add to the collective body of medical knowledge concerning the best ways to treat pain and improve patient quality of life, however, Defendants instead sought to distort medical and public perception of existing scientific data.

212. As explained more fully herein, Defendants, collectively and individually, poured vast sums of money into generating articles, continuing medical education courses (“CMEs”), and other “educational” materials, conducting sales visits to individual doctors, and supporting a network of professional societies and advocacy groups, which was intended to, and which did, create a new but phony “consensus” supporting the long-term use of opioids.

1. Defendants’ Corruption of Scientific Literature

213. Rather than actually test the safety and efficacy of opioids for long-term use, Defendants led physicians, patients, and health care payors to believe that such tests had already been done. As set forth herein, Defendants created a body of false, misleading, and unsupported medical and popular literature about opioids that (a) understated the risks and overstated the benefits of long-term use; (b) appeared to be the result of independent, objective research; and (c) was likely to shape the perceptions of prescribers, patients, and payors. This literature was, in fact, marketing material intended to persuade doctors and consumers that the benefits of long-term opioid use outweighed the risks.

214. To accomplish their goal, Defendants – sometimes through third-party consultants and/or front groups – commissioned, edited, and arranged for the placement of favorable articles in academic journals.

215. Defendants’ plans for these materials did not originate in the departments within the Defendant organizations that were responsible for research, development, or any other area that would have specialized knowledge about the drugs and their effects on patients; rather, they originated in Defendants’ marketing departments and with Defendants’ marketing and public relations consultants.

216. In these materials, Defendants (or their surrogates) often claimed to rely on “data on file” or presented posters, neither of which are subject to peer review. Still, Defendants

presented these materials to the medical community as scientific articles or studies, despite the fact that Defendants' materials were not based on reliable data and subject to the scrutiny of others who are experts in the same field.

217. Defendants also made sure that favorable articles were disseminated and cited widely in the medical literature, even when Defendants knew that the articles distorted the significance or meaning of the underlying study. Most notably, Purdue frequently cited a 1980 item in the well-respected New England Journal of Medicine, J. Porter & H. Jick, *Addiction Rare in Patients Treated with Narcotics*, 302 (2) New Eng. J. Med. 123 (1980) ("Porter & Jick Letter"), in a manner that makes it appear that the item reported the results of a peer reviewed study. It is also cited in two CME programs sponsored by Endo. Defendants and those acting on their behalf failed to reveal that this "article" is actually a letter-to-the-editor, not a study, much less a peer-reviewed study. The letter, reproduced in full below, states that the authors examined their files of hospitalized patients who had received opioids.

ADDICTION RARE IN PATIENTS TREATED WITH NARCOTICS

To the Editor: Recently, we examined our current files to determine the incidence of narcotic addiction in 39,946 hospitalized medical patients¹ who were monitored consecutively. Although there were 11,882 patients who received at least one narcotic preparation, there were only four cases of reasonably well documented addiction in patients who had no history of addiction. The addiction was considered major in only one instance. The drugs implicated were meperidine in two patients,² Percodan in one, and hydromorphone in one. We conclude that despite widespread use of narcotic drugs in hospitals, the development of addiction is rare in medical patients with no history of addiction.

JANE PORTER

HERSHEL JICK, M.D.

**Boston Collaborative Drug
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1. Jick H, Miettinen OS, Shapiro S, Lewis GP, Siskind Y, Slone D.

Comprehensive drug surveillance. JAMA. 1970; 213-1455-60.

2. Miller RR, Jick H. Clinical effects of meperidine in hospitalized medical patients. J Clin Pharmacol. 1978; 18:180-8.

218. The patients referred to in the letter were all treated prior to the letter, which was published in 1980. Because of standards of care prior to 1980, the treatment of those patients with opioids would have been limited to acute or end-of-life situations, not chronic pain. The letter notes that, when these patients' records were reviewed, the authors found almost no references to signs of addiction, though there is no indication that caregivers were instructed to look for, assess, or document signs of addiction. Nor, indeed, is there any indication whether the patients were followed after they were discharged from the hospital or, if they were, for how long. None of these serious limitations was disclosed when Defendants and those acting on their behalf cited the letter, typically as the sole scientific support for the proposition that opioids are rarely addictive.

219. Dr. Jick has complained that his letter has been distorted and misused – as indeed it has.

220. Defendants worked to not only create and promote favorable studies in the literature, but to discredit or suppress negative information. Defendants' studies and articles often targeted articles that contradicted Defendants' claims or raised concerns about chronic opioid therapy. In order to do so, Defendants – often with the help of third- party consultants – used a broad range of media to get their message out, including negative review articles, letters to the editor, commentaries, case-study reports, and newsletters.

221. Defendants' strategy – to plant and promote supportive literature and then to cite the pro-opioid evidence in their promotional materials, while failing to disclose evidence that contradicted those claims – was flatly inconsistent with their legal obligations. The strategy was intended to, and did, distort prescribing patterns by distorting the truth regarding the risks and benefits of opioids for chronic pain relief.

2. Defendants' Misuse of Treatment Guidelines

222. Treatment guidelines have been particularly important in securing acceptance for chronic opioid therapy. They are relied upon by doctors, especially the general practitioners and

family doctors targeted by Defendants, who are generally not experts, and who generally have no special training, in the treatment of chronic pain. Treatment guidelines not only directly inform doctors' prescribing practices, but also are cited throughout scientific literature and relied on by third-party payors in determining whether they should pay for treatments for specific indications.

a. Federation of State Medical Boards (FSMB)

223. The Federation of State Medical Boards ("FSMB") is a trade organization representing the various state medical boards in the United States. The state boards that comprise the FSMB membership have the power to license doctors, investigate complaints, and discipline physicians. The FSMB finances opioid- and pain-specific programs through grants from Defendants.

224. Since 1998, the FSMB has been developing treatment guidelines for the use of opioids for the treatment of pain. The 1998 version, Model Guidelines for the Use of Controlled Substances for the Treatment of Pain ("1998 Guidelines") was produced "in collaboration with pharmaceutical companies" and taught not that opioids could be appropriate in limited cases after other treatments had failed, but that opioids were "essential" for treatment of chronic pain, including as a first prescription option.

225. A 2004 iteration of the 1998 Guidelines and the 2007 book, Responsible Opioid Prescribing, also made the same claims as the 1998 Guidelines. These guidelines were posted online and were available to and intended to reach physicians nationwide, including in this district.

226. The publication of Responsible Opioid Prescribing was backed largely by drug manufacturers. In all, 163,131 copies of Responsible Opioid Prescribing were distributed by state medical boards (and through the boards, to practicing doctors). The FSMB website describes the book as the "leading continuing medication (CME) activity for prescribers of opioid medications."

227. Defendants relied on 1998 Guidelines to convey the alarming message that "under-treatment of pain" would result in official discipline, but no discipline would result if opioids were prescribed as part of an ongoing patient relationship and prescription decisions were

documented. FSMB turned doctors' fear of discipline on its head: doctors, who used to believe that they would be disciplined if their patients became addicted to opioids, were taught instead that they would be punished if they failed to prescribe opioids to their patients with chronic pain.

b. AAPM/APS Guidelines

228. American Academy of Pain Medicine ("AAPM") and the American Pain Society ("APS") are professional medical societies, each of which received substantial funding from Defendants from 2009 to 2013. In 1997, AAPM issued a "consensus" statement that endorsed opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low.⁵⁸ The Chair of the committee that issued the statement, Dr. J. David Haddox, was at the time a paid speaker for Purdue. The sole consultant to the committee was Russell Portenoy. The consensus statement, which also formed the foundation of the 1998 Guidelines, was published on the AAPM's website.

229. AAPM and APS issued their own guidelines in 2009 ("2009 Guidelines") and continued to recommend the use of opioids to treat chronic pain. Fourteen of the 21 panel members who drafted the 2009 Guidelines, including KOLs Dr. Portenoy and Dr. Fine, received support from Defendants Janssen, Cephalon, Endo, and Purdue.

230. The 2009 Guidelines promote opioids as "safe and effective" for treating chronic pain and conclude that the risk of addiction is manageable for patients regardless of past abuse histories. The 2009 Guidelines have been a particularly effective channel of deception and have influenced not only treating physicians, but also the body of scientific evidence on opioids; they were reprinted in the *Journal of Pain*, have been cited hundreds of times in academic literature, were disseminated in nationwide and in this district during the relevant time period, and were and are available online.

231. Defendants widely cited and promoted the 2009 Guidelines without disclosing

⁵⁸ The Use of Opioids for the Treatment of Chronic Pain, APS & AAPM (1997). Available at <http://opi.areastematicas.com/generalidades/OPIOIDES.DOLORCRONICO.pdf>.

the lack of evidence to support their conclusions.

c. Guidelines that Did Not Receive Defendants' Support

232. The extent of Defendants' influence on treatment guidelines is demonstrated by the fact that independent guidelines – the authors of which did not accept drug company funding – reached very different conclusions.

233. The 2012 Guidelines for Responsible Opioid Prescribing in Chronic Non- Cancer Pain, issued by the American Society of Interventional Pain Physicians (“ASIPP”), warned that “[t]he recent revelation that the pharmaceutical industry was involved in the development of opioid guidelines as well as the bias observed in the development of many of these guidelines illustrate that the model guidelines are not a model for curtailing controlled substance abuse and may, in fact, be facilitating it.” ASIPP’s Guidelines further advise that “therapeutic opioid use, specifically in high doses over long periods of time in chronic non-cancer pain starting with acute pain, not only lacks scientific evidence, but is in fact associated with serious health risks including multiple fatalities, and is based on emotional and political propaganda under the guise of improving the treatment of chronic pain.” ASIPP recommends long-acting opioids in high doses only “in specific circumstances with severe intractable pain” and only when coupled with “continuous adherence monitoring, in well-selected populations, in conjunction with or after failure of other modalities of treatments with improvements in physical and functional status and minimal adverse effects.”⁵⁹

234. Similarly, the 2011 Guidelines for the Chronic Use of Opioids, issued by the American College of Occupational and Environmental Medicine, recommend against the “routine use of opioids in the management of patients with chronic pain,” finding “at least moderate

⁵⁹Laxmaiah Manchikanti, et al., American Society of Interventional Pain Physicians (ASIPP) *Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain: Part 1, Evidence Assessment*, 15 Pain Physician (Special Issue) S1-S66; *Part 2 – Guidance*, 15 Pain Physician (Special Issue) S67-S116 (2012).

evidence that harms and costs exceed benefits based on limited evidence.”⁶⁰

235. The Clinical Guidelines on Management of Opioid Therapy for Chronic Pain, issued by the U.S. Department of Veterans Affairs (“VA”) and Department of Defense (“DOD”) in 2010, notes that their review revealed a lack of solid evidence-based research on the efficacy of long-term opioid therapy.⁶¹

E. DEFENDANTS’ PROMOTION OF THEIR OPIOID DRUGS WAS ALSO DECEPTIVE

236. While Defendants worked in concert to expand the market for opioids, they also worked to maximize their individual shares of that market. Each Defendant promoted opioids for chronic pain through sales representatives (which Defendants called “detailers” to deemphasize their primary sales role) and small group speaker programs to reach out to individual prescribers nationwide and in this district. By establishing close relationships with doctors, Defendants were able to disseminate their misrepresentations in targeted, one-on-one settings that allowed them to differentiate their opioids and to allay individual prescribers’ concerns about prescribing opioids for chronic pain.

237. Defendants developed sophisticated methods for selecting doctors for sales visits based on the doctors’ prescribing habits. In accordance with common industry practice, Defendants purchase and closely analyze prescription sales data from IMS Health, a healthcare data collection, management and analytics corporation. This data allows them to track precisely the rates of initial and renewal prescribing by individual doctors, which allows them to target and tailor their appeals. Sales representatives visited hundreds of thousands of doctors and disseminated the misinformation and materials described above throughout the United States, including doctors in this district.

F. Defendants Knew That Their Marketing of Chronic Opioid Therapy Was

⁶⁰ *American College of Occupational and Environmental Medicine’s Guidelines for the Chronic Use of Opioids* (2011).

⁶¹ Management of Opioid Therapy for Chronic Pain Working Group, VA/DoD Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain (May 2010). Available at http://www.healthquality.va.gov/guidelines/Pain/cot/COT_312_Full-er.pdf.

False, Unfounded, and Dangerous and Would Harm Plaintiff

238. Defendants made, promoted, and profited from their misrepresentations – individually and collectively – knowing that their statements regarding the risks, benefits, and superiority of opioids for chronic pain were false and misleading. Cephalon and Purdue entered into settlements in the hundreds of millions of dollars to resolve criminal and federal charges involving nearly identical conduct. Defendants had access to scientific studies, detailed prescription data, and reports of adverse events, including reports of addiction, hospitalization, and deaths – all of which made clear the significant adverse outcomes from opioids and that patients were suffering from addiction, overdoses, and death in alarming numbers. Defendants expected and intended that their misrepresentations would induce doctors to prescribe, patients to use, and third-party payors to pay for their opioids for chronic pain.

239. When they began their deceptive marketing practices, Defendants recklessly disregarded the harm that their practices were likely to cause. As their scheme was implemented, and as reasonably foreseeable harm began to occur, Defendants were well aware that it was occurring. Defendants closely monitored their own sales and the habits of prescribing doctors, which allowed them to see sales balloon – overall, in individual practices, and for specific indications. Their sales representatives, who visited doctors and attended CME programs, knew what types of doctors were receiving their messages and how they were responding. Moreover, Defendants had access to, and carefully monitored government and other data that tracked the explosive rise in opioid use, addiction, injury, and death.

G. Defendants Entered into and Engaged in a Civil Conspiracy

240. Defendants entered into a conspiracy to engage in the wrongful conduct complained of herein, and intended to benefit both independently and jointly from their conspiratorial enterprise.

241. Defendants reached an agreement between themselves to set up, develop, and fund an unbranded promotion and marketing network to promote the use of opioids for the management of pain in order to mislead physicians, patients, health care providers, and health care payors

through misrepresentations or omissions regarding the appropriate uses, risks and safety of opioids.

242. This network is interconnected and interrelated, and relied upon Defendants' collective use of and reliance upon unbranded marketing materials, such as KOLs, scientific literature, CMEs, patient education materials, and Front Groups. These materials were developed and funded collectively by Defendants, and Defendants relied upon the materials to intentionally mislead consumers, payors, and medical providers of the appropriate uses, risks and safety of opioids.

243. By knowingly misrepresenting the appropriate uses, risks, and safety of opioids, Defendants committed overt acts in furtherance of their conspiracy.

V. CAUSES OF ACTION

COUNT I
VIOLATION OF 18 U.S.C § 1962(c), OPIOID DRUGS
PROMOTION ENTERPRISE, PURSUANT TO THE
RACKETEER INFLUENCED AND CORRUPT PRACTICES ACT
(AGAINST ALL DEFENDANTS)

244. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein.

245. Defendants are persons" within the meaning of 18 U.S.C. § 1961(3) who conducted the affairs of the enterprise, the Opioid Drugs Promotion Enterprise, through a pattern of racketeering activity in violation of 18 U.S.C. § 1962(c).

246. The Opioid Drugs Promotion Enterprise is an association-in-fact within the meaning of 18 U.S.C. § 1961(4), consisting of Defendants, including their employees and agents; Front Groups, including their employees and agents; and KOL's; as well as external and other as yet unknown marketing firms and distribution agents employed by Defendants in furtherance of the Opioid Drugs Promotion Enterprise. All entities are persons within the meaning of 18 U.S.C. § 1961(3) and acted to enable Defendants to fraudulently market Opioid drugs as scientifically proven as safe and effective. The Opioid Drugs Promotion Enterprise is an organization that functioned as an ongoing organization and continuing unit. The Opioid Drugs Promotion

Enterprise was created and organized to effectuate a pattern of racketeering activity, and maintained systematic links for a common purpose: to ensure the prescription opioids for chronic pain. Each of these entities, including the Defendants, is a "person" distinct from the Opioid Drugs Promotion Enterprise.

247. Each of the Defendants, in concert with the Front Groups, KOL's as well as external and other as yet unknown marketing firms and distribution agents employed by Defendants in furtherance of the Opioid Drugs Promotion Enterprise, created and maintained systematic links for a common purpose-to aid in marketing Opioid drugs as safe for treatment of chronic pain, while suppressing evidence to the contrary and improperly inducing physicians to prescribe Opioid drugs for chronic pain. Each of the participants in the Opioid Drugs Promotion Enterprise received substantial revenue from the scheme to promote Opioid drugs as safe for its intended uses. Such revenue was exponentially greater than it would have been if Opioid drugs was marketed appropriately and the true safety risks of Opioid drugs disclosed. All participants of the Opioid Drugs Promotion Enterprise were aware of Defendants' control over the activities of the Opioid Drugs Promotion Enterprise in promoting Opioid drugs. Furthermore, each portion of the enterprise benefited from the existence of the other parts.

248. The Opioid Drugs Promotion Enterprise engaged in and affected interstate commerce, because *inter alia*, it marketed, promoted, sold, or provided Opioid drugs to thousands of individuals and entities throughout the United States.

249. The named Defendants exerted control over the Opioid Drugs Promotion Enterprise and management of the affairs of the Opioid Drugs Promotion Enterprise.

250. Defendants conducted and participated in the affairs of the Opioid Drugs Promotion Enterprise through patterns of racketeering activity that includes acts indictable under 18 U.S.C. § 1341 (mail fraud), § 1343 (wire fraud), § 1512 (tampering with witnesses), and § 1952 (use of interstate facilities to conduct unlawful activity).

251. Defendants fraudulent scheme consisted of, *inter alia*: deliberately misrepresenting the safety of Opioid Drugs so that Plaintiff paid for this drug for pain treatment

and actively concealing and causing others to conceal, information about the true safety of Opioid drugs for such pain treatment. The Opioid Drugs Promotion Enterprise concealed from the public, consumers, prescribers, and TPP's the serious risks and lack of corresponding benefits of using opioids for chronic pain. By making those representations, the Opioid Drugs Promotion Enterprise ensured that a larger number of opioid prescriptions would be written and filled for chronic pain. This translated into higher sales (and therefore profits) for Defendants.

252. The persons engaged in the Opioid Drugs Promotion Enterprise are systematically linked through contractual relationships, financial ties, and continuing coordination of activities, as spearheaded by Defendants. There is regular communication between Defendants, Front Groups and KOLs, in which information is shared. Typically, this communication occurred, and continues to occur, through the use of the wires and the mail in which Defendants, Front Groups and KOLs share information regarding overcoming objections to the use of opioids for chronic pain. Defendants, the Front Groups and KOLs functioned as a continuing unit for the purposes of implementing the Opioid Drugs Promotion Enterprise scheme and, when issues arise during the scheme, each agreed to take actions to hide the scheme and continue the Opioid Drugs Promotion Enterprise existence.

253. At all relevant times, Front Groups were aware of Defendants' conduct, were a knowing and willing participant in that conduct, and reaped benefits from that conduct. Each Front Groups also knew, but did not disclose, that the other Front Groups were engaged in the same scheme, to the detriment of consumers and TPP's including Plaintiff. But for the Opioid Drugs Promotion Enterprise's unlawful fraud, Front Groups would have had the incentive to disclose the deceit by Defendants to their members and constituents. By failing to disclose this information, Front Groups perpetuated the Opioid Drugs Promotion Enterprise's scheme, and reaped substantial benefits.

254. At all relevant times, KOLs were aware of Defendants' conduct, were knowing and willing participants in that conduct, and reaped profits from that conduct. Defendants selected

KOLs solely because they favored the aggressive treatment of chronic pain with opioids. Defendants' support helped these doctors become respected industry experts. And, as they rose to prominence, these doctors touted the benefits of opioids to treat chronic pain, repaying Defendants by advancing their marketing goals. The KOLs also knew, but did not disclose, that the other KOLs and Front Groups were engaged in the same scheme, to the detriment of consumers and TPP's including Plaintiff. Opioid Drugs Promotion Enterprise's unlawful fraud, KOLs would have been incentivized to disclose the deceit, and to protect their patients and the patients of other physicians. By failing to disclose this information, KOLs perpetuated the Opioid Drugs Promotion Enterprise's scheme, and reaped substantial benefits.

255. Furthermore, as public scrutiny and media coverage have focused on how opioids have ravaged communities in New York, and throughout the United States, the Front Groups and KOLs did not challenge Defendants' misrepresentations, terminate their role in the Opioid Drugs Promotion Enterprise, nor disclose publicly that the risks of using opioids for chronic pain outweighed their benefits.

256. The Front Groups and KOLs participated in the conduct of the Opioid Drugs Promotion Enterprise, sharing the common purpose of marketing opioids for chronic pain and, through a pattern of racketeering activity, which includes multiple instances of mail fraud, and multiple instances of wire fraud, they knowingly made material misstatements or omissions as set forth herein above to New York physicians, consumers, TPP's and the general public in furtherance of the fraudulent scheme.

257. Defendants' use of the mails and wires to perpetuate their fraud involved thousands of communications, including, but not limited to:

- a. communications with and among the enterprise participants that misrepresented the safety and risks of Opioid drugs amongst themselves and others;
- b. communications with patients, including Plaintiff, inducing payments for Opioid drugs by misrepresenting the safety and risks of Opioid drugs;
- c. receiving the proceeds in the course of and resulting from Defendants' improper scheme;

- d. transmittal and receipt of monies from TPP's including without limitation Plaintiff, as well as governmental health organizations and programs, including without limitation Medicare and Medicaid; and
- e. transmittal and receipt of payments in exchange for, directly or indirectly, activities in furtherance of the Opioid Drugs Promotion Enterprise.

258. At all times during the fraudulent scheme, Defendants and the Fraud Participants including without limitation the KOL's and the Front Groups had a legal and ethical obligation of candor to and honest dealing with public and TPP's, physicians and the medical community.

259. The conduct of the Opioid Drugs Promotion Enterprise described above constitutes "racketeering activity" within the meaning of 18 U.S.C. § 1961(1). Defendants' decisions and activity in connection with the Opioid Drugs Promotion Enterprise to routinely conduct its transactions in such a manner constitutes a "pattern of racketeering activity" within the meaning of 18 U.S.C. § 1961(5).

260. The above described racketeering activities amounted to a common course of conduct intended to deceive and harm Plaintiff. Each such racketeering activity was related had similar purposes, involved similar or the same participants, and methods of commission, and had similar results affecting the same or similar victims, including Plaintiff. Defendants' racketeering activities were part of their ongoing business and constitute a continuing threat to the property of Plaintiff.

261. Plaintiff has been injured in their property by reason of these violations in that Plaintiff paid hundreds of millions of dollars for Opioid drugs, and for treatment related to opioid addiction and abuse that they would not have paid had Defendants not engaged in this pattern of racketeering activity.

262. The injuries to Plaintiff were directly and proximately caused by Defendants' racketeering activity.

263. Patients, physicians, PBMs, pharmacy and therapeutic committee members, and third-party payors, including Plaintiff, directly relied on the racketeering activities of the Defendants and the Opioid Drugs Promotion Enterprise. Plaintiff, both directly and indirectly,

relied on the representations as to the efficacy and safety of Opioid drugs as promoted by Defendants. Because Defendants controlled all knowledge of the tests upon which the claims of Opioid drugs' efficacy and safety were based, as well as other members of the medical community and consuming public were obligated to rely on Defendants' and the Opioid Drugs Promotion Enterprise's representations about Opioid drugs. Further, Defendants perpetuated this reliance by taking the steps itemized above to suppress the dissemination of any critical information about the use of Opioid drugs for chronic pain.

264. By virtue of these violations of 18 U.S.C. § 1962(c) Defendants are liable to Plaintiff for three times the damages sustained, plus the costs of this suit, including reasonable attorney's fees.

265. By reason of the foregoing, and as a direct and proximate result of Defendants' fraudulent misrepresentations, Plaintiff have suffered damages. Plaintiff is entitled to compensatory damages, equitable and declaratory relief, punitive damages, costs and reasonable attorneys' fees.

266. By reason of the foregoing, Plaintiff has been damaged as against the Defendants in a sum that exceeds the jurisdiction of all lower courts.

WHEREFORE, Plaintiff, LABORERS 17 HEALTH BENEFIT FUND, prays for judgment against Defendants, PURDUE PHARMA, L.P., PURDUE PHARMA, INC., THE PURDUE FREDERICK COMPANY, INC., TEVA PHARMACEUTICALS INDUSTRIES, LTD., TEVA PHARMACEUTICALS USA, INC., CEPHALON, INC., JOHNSON & JOHNSON, JANSSEN PHARMACEUTICALS, INC., ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., n/k/a JANSSEN PHARMACEUTICALS, INC., JANSSEN PHARMACEUTICA, INC., n/k/a JANSSEN PHARMACEUTICALS, INC., NORAMCO, INC., ENDO HEALTH SOLUTIONS, INC., ENDO PHARMACEUTICALS, INC., QUALITEST PHARMACEUTICALS, INC., ALLERGAN PLC, f/k/a ACTAVIS PLC, WATSON PHARMACEUTICALS, INC., n/k/a

ACTAVIS, INC., WATSON LABORATORIES, INC., ACTAVIS LLC, ACTAVIS PHARMA, INC., f/k/a WATSON PHARMA, INC., MALLINCKRODT PLC, MALLINCKRODT LLC, MCKESSON CORPORATION, CARDINAL HEALTH INC., AMERISOURCEBERGEN DRUG CORPORATION, ABBOTT LABORATORIES, INC., RUSSELL PORTENOY, PERRY FINE, SCOTT FISHMAN, and LYNN WEBSTER, for damages in excess of Seventy-Five Thousand Dollars (\$75,000), for statutory damages, for attorneys' fees and costs expended herein, for punitive damages, for interest, and for such other and further relief both at law and in equity to which Plaintiff may show to be justly entitled, and demand a trial by jury of all issues triable as a matter of right by a jury.

COUNT II
VIOLATION OF 18 U.S.C. § 1962(d) – RICO CONSPIRACY PURSUANT
TO THE RACKETEER INFLUENCED AND CORRUPT PRACTICES ACT
(AGAINST ALL DEFENDANTS)

267. Plaintiff incorporate by reference all preceding paragraphs as if fully set forth herein.

268. Section 1962(d) of RICO provides that it "shall be unlawful for any person to conspire to violate any of the provision of subsection (a), (b), or (c) of this section."

269. Defendants have violated § 1962(d) by conspiring to violate 18 U.S.C. § 1962(c). The object of this conspiracy has been and is to conduct or participate in, directly or indirectly, the conduct of the affairs of the Opioid Drugs Promotion Enterprise described previously through a pattern of racketeering activity. The defendants conspired with, *inter alia*, publicists, sales representatives, medical professionals, the KOL's, the Front Groups, academics and other intermediaries to promote Opioid drugs for chronic pain, and suppress information about the harms known to result from Opioid drugs use.

270. Defendants' co-conspirators have engaged in numerous overt and predicate fraudulent racketeering acts in furtherance of the conspiracy, including material misrepresentations and omissions designed to defraud Plaintiff of money.

271. The nature of the above-described Defendants' co-conspirators' acts, material misrepresentations, and omissions in furtherance of the conspiracy gives rise to an inference that they not only agreed to the objective of an 18 U.S.C. § 1962(d) violation of RICO by conspiring to violate 18 U.S.C. § 1962(c), but they were aware that their ongoing fraudulent and extortionate acts have been and are part of an overall pattern of racketeering activity.

272. As a direct and proximate result of Defendants' overt acts and predicate acts in furtherance of violating 18 U.S.C. § 1962(d) by conspiring to violate 18 U.S.C. § 1962(c), Plaintiff has been and is continuing to be injured in their business or property as set forth more fully above.

273. Defendants sought to and have engaged in the commission of and continue to commit overt acts, including the following unlawful racketeering predicate acts:

- a. Multiple instances of mail and wire fraud violations of 18 U.S.C. §§ 1341 and 1342;
- b. Multiple instances of mail fraud violation of 18 U.S.C. §§ 1341 and 1346;
- c. Multiple instances of wire fraud violations of 18 U.S.C. §§ 1341 and 1346;
- d. Multiple instances of unlawful activity in violation of 18 U.S.C. § 1952.

274. Defendants' violations of the above federal laws and the effects thereof detailed above are continuing and, upon information and belief, will continue into the future unless enjoined by this Court.

275. Plaintiff has been injured in its property by reason of these violations in that Plaintiff has made paid hundreds of millions of dollars for Opioid drugs; and the treatment related to the misuse, addiction and/or overdose of Opioid drugs that it would not have made had Defendants not conspired to violate 18 U.S.C. § 1962(c).

276. Injuries suffered by Plaintiff were directly and proximately caused by Defendants' racketeering activity as described above.

277. Patients, physicians, PBMs, pharmacy and therapeutic committee members, and

third-party payors, including Plaintiff, directly relied on the racketeering activities of the Defendants' and the Opioid Drugs Promotion Enterprise. Plaintiff, both directly and indirectly, relied on the representations as to the efficacy and safety of Opioid drugs as promoted by Defendants. Because Defendants controlled all knowledge of the tests upon which the claims of Opioid drug's efficacy and safety were based, Plaintiff, as well as other members of the medical and consuming public were obligated to rely on Defendants' representations about Opioid drugs. Further, Defendants perpetuated this reliance by taking the steps itemized above to suppress the dissemination of any critical information about Opioid drugs.

278. By virtue of these violations of 18 U.S.C. § 1962(d), Defendants are liable to Plaintiff for three times the damages Plaintiff has sustained, plus the cost of this suit, including reasonable attorney's fees.

279. By reason of the foregoing, and as a direct and proximate result of Defendants' fraudulent misrepresentations, Plaintiff has suffered damages. Plaintiff is entitled to compensatory damages, equitable and declaratory relief, punitive damages, costs and reasonable attorneys' fees.

280. By reason of the foregoing, Plaintiff has been damaged as against the Defendant in a sum that exceeds the jurisdiction of all lower courts.

WHEREFORE, Plaintiff, LABORERS 17 HEALTH BENEFIT FUND, prays for judgment against Defendants, PURDUE PHARMA, L.P., PURDUE PHARMA, INC., THE PURDUE FREDERICK COMPANY, INC., TEVA PHARMACEUTICALS INDUSTRIES, LTD., TEVA PHARMACEUTICALS USA, INC., CEPHALON, INC., JOHNSON & JOHNSON, JANSSEN PHARMACEUTICALS, INC., ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., n/k/a JANSSEN PHARMACEUTICALS, INC., JANSSEN PHARMACEUTICA, INC., n/k/a JANSSEN PHARMACEUTICALS, INC., NORAMCO, INC., ENDO HEALTH SOLUTIONS, INC., ENDO PHARMACEUTICALS, INC., QUALITEST PHARMACEUTICALS, INC., ALLERGAN PLC, f/k/a ACTAVIS PLC, WATSON PHARMACEUTICALS, INC., n/k/a

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COUNT III
CLAIM AGAINST DEFENDANTS FOR VIOLATIONS OF THE
NEW YORK DECEPTIVE PRACTICES ACT, N.Y. G.B.L. § 349
(AGAINST ALL DEFENDANTS)

281. Plaintiff incorporate by reference all preceding paragraphs as if fully set forth herein.

282. At times material hereto, the Manufacturer and Distributor Defendants, along with the Key Opinion Leaders they assisted and controlled, falsely and/or carelessly misrepresented to the general public, including to Plaintiff, the dangers of long-term opioid use to physicians, pharmacists, and patients by engaging in a campaign to minimize the risks of, and to encourage, long-term opioid use.

283. The Defendants engaged in an intentional, decades-long pattern of unfair and deceptive acts relating to the efficacy of their respective opioid drugs, intentionally diminishing the associated health hazards and conspiring with key opinion leaders to increase their sales and profits despite the known risks and dangerous propensity of their drugs.

284. The Defendants intentionally overstated the benefits and downplayed the risks of the use of their opioids and aggressively marketed (directly and through key opinion leaders) these drugs to physicians and the Defendant distributors failed to monitor, detect, investigate, refuse and

report suspicious orders of prescription opiates as required under the Controlled Substances Act.

285. The representations by said Defendants were false, misleading and/or deceptive. In contrast, the Defendants knew their opioids were addictive, were not safe to be used for long-term chronic pain treatment, were being diverted and misused and were, in fact, dangerous and hazardous to the health and body of its users.

286. The New York Deceptive Practices, N.Y. G.B.L. § 349 (“NYDPA”), prohibits all “[d]eceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service in [New York] state.” In order to state a claim under the NYDPA, a plaintiff “must prove three elements: first, that the challenged act or practice was consumer-oriented; second, that it was misleading in a material way; and third, that the plaintiff suffered injury as a result of the deceptive act.” *Stutman v. Chem. Bank*, 95 N.Y.2d 24, 29, 709 N.Y.S.2d 892, 731 N.E.2d 608 (N.Y. 2000).

287. Through their conduct described above, the Defendants have engaged in unconscionable and deceptive acts and practices in violation of the NYDPA, the stated terms and intent of which is to protect consumers from unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce.

288. Representing that their representative prescription opioids were, in fact, safe is deceptive and has the capacity and tendency and effect of deceiving reasonable consumers who purchase and use the products, including members of Plaintiff Laborers 17. Reasonable consumers would believe that prescription opioids were safe to use for its intended purpose as a pain management treatment, based upon the Defendants’ misrepresentations to that effect.

289. Plaintiff, and its constituent members, relied on the Defendants’ deceptive representations to its/their detriment.

290. The Defendants made, and make, the representation that their prescription opioid drugs are a safe method of treating long-term chronic pain conditions.

291. Plaintiff has been aggrieved and has suffered losses as a result of the Defendants’ violations of NYDPA. By virtue of the foregoing unfair, unconscionable, and deceptive acts in the

conduct of trade or commerce. Plaintiff has paid and/or provided reimbursement for some or the entire purchase price on behalf of its members for prescription opioids, which are manufactured, marketed, promoted, sold, and/or distributed by the Defendants. Plaintiff has sustained injury as a direct and proximate result of Defendants' illegal and wrongful conduct alleged herein and seeks recovery of any and all costs, damages or losses sustained as a result of the provision of care, services and/or supplies, including, but not limited to, the delivery of prescription opioid medications, treatments, hospitalizations, addiction and rehabilitation treatment, overdose or other opioid-related services.

292. The Defendants continue to violate NYDPA through the present day.

293. By reason of the foregoing, the Defendants have violated NYDPA and are liable to Plaintiff for the damages that it has suffered as a result of the Defendants' actions, the amount of such damages to be determined at trial, attorneys' fees and costs, and punitive damages. Plaintiff further demands injunctive relief enjoining the Defendants from continuing to engage in, use, or employ any act, including advertisements, packaging, or other representations, prohibited by NYDPA.

WHEREFORE, Plaintiff, LABORERS 17 HEALTH BENEFIT FUND, prays for judgment against Defendants, PURDUE PHARMA, L.P., PURDUE PHARMA, INC., THE PURDUE FREDERICK COMPANY, INC., TEVA PHARMACEUTICALS INDUSTRIES, LTD., TEVA PHARMACEUTICALS USA, INC., CEPHALON, INC., JOHNSON & JOHNSON, JANSSEN PHARMACEUTICALS, INC., ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., n/k/a JANSSEN PHARMACEUTICALS, INC., JANSSEN PHARMACEUTICA, INC., n/k/a JANSSEN PHARMACEUTICALS, INC., NORAMCO, INC., ENDO HEALTH SOLUTIONS, INC., ENDO PHARMACEUTICALS, INC., QUALITEST PHARMACEUTICALS, INC., ALLERGAN PLC, f/k/a ACTAVIS PLC, WATSON PHARMACEUTICALS, INC., n/k/a

ACTAVIS, INC., WATSON LABORATORIES, INC., ACTAVIS LLC, ACTAVIS PHARMA, INC., f/k/a WATSON PHARMA, INC., MALLINCKRODT PLC, MALLINCKRODT LLC, MCKESSON CORPORATION, CARDINAL HEALTH INC., AMERISOURCEBERGEN DRUG CORPORATION, ABBOTT LABORATORIES, INC., RUSSELL PORTENOY, PERRY FINE, SCOTT FISHMAN, and LYNN WEBSTER, for damages in excess of Seventy-Five Thousand Dollars (\$75,000), for monetary, compensatory, treble and punitive damages, injunctive relief, restitution and disgorgement of all moneys obtained by means of the Defendants' unlawful conduct, interest and attorneys' fees and costs, and for such other and further relief both at law and in equity to which Plaintiff may show to be justly entitled, and demand a trial by jury of all issues triable as a matter of right by a jury.

COUNT IV
CLAIM OF FRAUDULENT CONCEALMENT
(AGAINST ALL DEFENDANTS)

294. Plaintiff incorporates by reference the allegations contained in the preceding paragraphs.

295. At all relevant times, the Manufacturer and Distributor Defendants, along with the Key Opinion Leaders they assisted and controlled, intentionally, willfully, and/or recklessly, with the intent to deceive, fraudulently concealed or omitted material information not otherwise known or available, knowing that the material was false or misleading, or failed to disclose a material fact concerning the health effects or addictive nature of their respective prescription opioid drugs or both.

296. At all relevant times, the Defendants misrepresented and/or concealed material facts concerning the addictive and dangerous nature of their prescription opioid drugs, to consumers, including Plaintiff, with the knowledge of the falsity of their misrepresentations.

297. At all relevant times, upon information and belief, the misrepresentations and concealments concerning their prescription opioid drugs that were manufactured, distributed, promoted and/or sold by the Defendants include, but are not limited to, the following:

- a. The Defendants intentionally misrepresented to Plaintiff and the public the truth about how opioids lead to addiction;
- b. The Defendants knowingly misrepresented that opioids improve function;
- c. The Defendants misrepresented that addiction risk can be managed;
- d. The Defendants misled doctors, patients, and payors through the use of misleading terms like “pseudoaddiction;”
- e. The Defendants falsely claimed that withdrawal is simply managed;
- f. The Defendants misrepresented that increased doses pose no significant additional risks;
- g. The Defendants falsely omitted or minimized the adverse effects of opioids and overstated the risks of alternative forms of pain treatment.

298. At all relevant times, the Defendants actively, knowingly, and intentionally concealed and misrepresented these material facts to the Plaintiff and the consuming public with the intent to deceive the Plaintiff and public, and with the intent that consumers would purchase and use their prescription opioid drugs.

299. At all relevant times, the consuming public, including Plaintiff, would not otherwise have purchased or used these addictive and dangerous opioid drugs for long-term chronic pain management they had been informed of the risks associated with the use of these drugs.

300. At all relevant times, Plaintiff relied on the Defendants’ misrepresentations concerning the safety and efficacy of these prescription opioid drugs, and its reliance was

reasonably justified.

301. As a direct and foreseeable consequence of Defendants' wrongful conduct, Plaintiff has incurred and continues to incur costs for opioid prescriptions in excess of those they would have otherwise incurred, payments for their insureds' treatment for opioid addiction, and payments for emergency hospital visits for their insureds' including payments for Naloxone Hydrochloride (Narcan) resulting from opioid abuse and overdose. Defendants' misrepresentations regarding the safety and efficacy of long-term opioid use proximately caused injury to Plaintiff.

WHEREFORE, Plaintiff, LABORERS 17 HEALTH BENEFIT FUND, prays for judgment against Defendants, PURDUE PHARMA, L.P., PURDUE PHARMA, INC., THE PURDUE FREDERICK COMPANY, INC., TEVA PHARMACEUTICALS INDUSTRIES, LTD., TEVA PHARMACEUTICALS USA, INC., CEPHALON, INC., JOHNSON & JOHNSON, JANSSEN PHARMACEUTICALS, INC., ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., n/k/a JANSSEN PHARMACEUTICALS, INC., JANSSEN PHARMACEUTICA, INC., n/k/a JANSSEN PHARMACEUTICALS, INC., NORAMCO, INC., ENDO HEALTH SOLUTIONS, INC., ENDO PHARMACEUTICALS, INC., QUALITEST PHARMACEUTICALS, INC., ALLERGAN PLC, f/k/a ACTAVIS PLC, WATSON PHARMACEUTICALS, INC., n/k/a ACTAVIS, INC., WATSON LABORATORIES, INC., ACTAVIS LLC, ACTAVIS PHARMA, INC., f/k/a WATSON PHARMA, INC., MALLINCKRODT PLC, MALLINCKRODT LLC, MCKESSON CORPORATION, CARDINAL HEALTH INC., AMERISOURCEBERGEN DRUG CORPORATION, ABBOTT LABORATORIES, INC., RUSSELL PORTENOY, PERRY FINE, SCOTT FISHMAN, and LYNN WEBSTER, for damages in excess of Seventy-Five Thousand Dollars (\$75,000), for interest, and for such other and further relief both at law and in equity to which Plaintiff may show to be justly entitled, and demand a trial by jury of all issues

triable as a matter of right by a jury.

COUNT V
CLAIM OF CONSPIRACY TO COMMIT FRAUD BY CONCEALMENT
(AGAINST ALL DEFENDANTS)

302. Plaintiff incorporates by reference the allegations contained in the preceding paragraphs.

303. At all relevant times, the Manufacturer and Distributor Defendants, along with the Key Opinion Leaders they assisted and controlled, agreed to conceal or omit information regarding the health effects or addictive nature of their respective prescription opioid drugs or both, with the intention that the Plaintiff and the public would rely on the information to their detriment.

304. The Defendants' actions, and those of the Key Opinion Leaders, constitute a successful conspiracy to commit fraud by concealment.

305. Specifically, Defendants agreed and conspired to misrepresent and/or conceal material facts concerning the addictive and dangerous nature of their prescription opioid drugs, to consumers, including Plaintiff, with the knowledge of the falsity of their misrepresentations.

306. At all relevant times, upon information and belief, the misrepresentations and concealments concerning their prescription opioid drugs that were manufactured, distributed, promoted and/or sold by the Defendants include, but are not limited to, the following:

- a. The Defendants intentionally misrepresented to Plaintiff and the public the truth about how opioids lead to addiction;
- b. The Defendants knowingly misrepresented that opioids improve function;
- c. The Defendants misrepresented that addiction risk can be managed;
- d. The Defendants misled doctors, patients, and payors through the use of misleading terms like “pseudoaddiction;”
- e. The Defendants falsely claimed that withdrawal is simply managed;

- f. The Defendants misrepresented that increased doses pose no significant additional risks;
- g. The Defendants falsely omitted or minimized the adverse effects of opioids and overstated the risks of alternative forms of pain treatment.

307. At all relevant times, the Defendants actively, knowingly, and intentionally agreed and conspired to conceal and misrepresent these material facts to the Plaintiff and the consuming public with the intent to deceive the Plaintiff and public, and with the intent that consumers would purchase and use their prescription opioid drugs.

308. At all relevant times, the consuming public, including Plaintiff, would not otherwise have purchased or used these addictive and dangerous opioid drugs for long-term chronic pain management they had been informed of the risks associated with the use of these drugs.

309. At all relevant times, Plaintiff relied on the Defendants' misrepresentations concerning the safety and efficacy of these prescription opioid drugs, and its reliance was reasonably justified.

310. As a direct and foreseeable consequence of Defendants' conspiracy to commit fraud by concealment, Plaintiff has incurred and continues to incur costs for opioid prescriptions in excess of those they would have otherwise incurred, payments for their insureds' treatment for opioid addiction, and payments for emergency hospital visits for their insureds' including payments for Naloxone Hydrochloride (Narcan) resulting from opioid abuse and overdose. Defendants' misrepresentations regarding the safety and efficacy of long-term opioid use proximately caused injury to Plaintiff.

WHEREFORE, Plaintiff, LABORERS 17 HEALTH BENEFIT FUND, prays for judgment

against Defendants, PURDUE PHARMA, L.P., PURDUE PHARMA, INC., THE PURDUE FREDERICK COMPANY, INC., TEVA PHARMACEUTICALS INDUSTRIES, LTD., TEVA PHARMACEUTICALS USA, INC., CEPHALON, INC., JOHNSON & JOHNSON, JANSSEN PHARMACEUTICALS, INC., ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., n/k/a JANSSEN PHARMACEUTICALS, INC., JANSSEN PHARMACEUTICA, INC., n/k/a JANSSEN PHARMACEUTICALS, INC., NORAMCO, INC., ENDO HEALTH SOLUTIONS, INC., ENDO PHARMACEUTICALS, INC., QUALITEST PHARMACEUTICALS, INC., ALLERGAN PLC, f/k/a ACTAVIS PLC, WATSON PHARMACEUTICALS, INC., n/k/a ACTAVIS, INC., WATSON LABORATORIES, INC., ACTAVIS LLC, ACTAVIS PHARMA, INC., f/k/a WATSON PHARMA, INC., MALLINCKRODT PLC, MALLINCKRODT LLC, MCKESSON CORPORATION, CARDINAL HEALTH INC., AMERISOURCEBERGEN DRUG CORPORATION, ABBOTT LABORATORIES, INC., RUSSELL PORTENOY, PERRY FINE, SCOTT FISHMAN, and LYNN WEBSTER, for damages in excess of Seventy-Five Thousand Dollars (\$75,000), for interest, and for such other and further relief both at law and in equity to which Plaintiff may show to be justly entitled, and demand a trial by jury of all issues triable as a matter of right by a jury.

COUNT VI
CLAIM OF NEGLIGENCE
(AGAINST MANUFACTURER DEFENDANTS)

311. Plaintiff incorporates by reference the allegations contained in the preceding paragraphs.

312. The Manufacturer Defendants, PURDUE PHARMA, L.P., PURDUE PHARMA, INC., THE PURDUE FREDERICK COMPANY, INC., TEVA PHARMACEUTICALS INDUSTRIES, LTD., TEVA PHARMACEUTICALS USA, INC., CEPHALON, INC., JOHNSON & JOHNSON, JANSSEN PHARMACEUTICALS, INC., ORTHO-MCNEIL-

JANSSEN PHARMACEUTICALS, INC., n/k/a JANSSEN PHARMACEUTICALS, INC., JANSSEN PHARMACEUTICA, INC., n/k/a JANSSEN PHARMACEUTICALS, INC., NORAMCO, INC., ENDO HEALTH SOLUTIONS, INC., ENDO PHARMACEUTICALS, INC., QUALITEST PHARMACEUTICALS, INC., ALLERGAN PLC, f/k/a ACTAVIS PLC, WATSON PHARMACEUTICALS, INC., n/k/a ACTAVIS, INC., WATSON LABORATORIES, INC., ACTAVIS LLC, ACTAVIS PHARMA, INC., f/k/a WATSON PHARMA, INC., MALLINCKRODT PLC and MALLINCKRODT LLC, at all times material, manufactured, designed, formulated, marketed, tested, promoted, supplied, sold, and/or distributed their respective prescription opioid drugs in the regular course of business.

313. At all relevant times, the Manufacturer Defendants had a duty to act with reasonable care in the design, development, marketing, labeling, manufacturing, formulating, testing, monitoring, distribution, and sale of their respective prescription opioid drugs.

314. At all relevant times, the Manufacturer Defendants had a duty to act with reasonable care and to warn the Plaintiff and the consuming public of the risk, dangers and addictive nature of their respective prescription opioid drugs.

315. At all relevant times, the Manufacturer Defendants knew or should have known that their respective prescription opioid drugs were unreasonably dangerous and defective for long-term chronic pain treatment and when used in a reasonably foreseeable manner.

316. The Manufacturer Defendants breached their duty to Plaintiff and were otherwise negligent in the design, development, marketing, labeling, manufacturing, formulating, testing, monitoring, distribution, and/or sale of their respective prescription opioid drugs, which were inherently dangerous and defective, and unfit and unsafe for their intended and reasonably foreseeable uses.

317. The Manufacturer Defendants were further negligent in failing to accompany their

respective prescription opioid drugs with proper warnings or adequate labeling regarding the dangerous and potentially fatal health risks associated with the use of their respective prescription opioid drugs, particularly when used for long-term chronic pain treatment, which was their intended or reasonably foreseeable use.

318. The Plaintiff is without fault and it would not have paid millions of dollars in inappropriate prescriptions but for the wrongful conduct of the Distributor Defendants.

319. The Distributor Defendants were a proximate cause of the over-prescription of the opioids and, hence, the millions of dollars in inappropriate prescriptions paid for by Plaintiff.

WHEREFORE, Plaintiff, LABORERS 17 HEALTH BENEFIT FUND, prays for judgment against Defendants, PURDUE PHARMA, L.P., PURDUE PHARMA, INC., THE PURDUE FREDERICK COMPANY, INC., TEVA PHARMACEUTICALS INDUSTRIES, LTD., TEVA PHARMACEUTICALS USA, INC., CEPHALON, INC., JOHNSON & JOHNSON, JANSSEN PHARMACEUTICALS, INC., ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., n/k/a JANSSEN PHARMACEUTICALS, INC., JANSSEN PHARMACEUTICA, INC., n/k/a JANSSEN PHARMACEUTICALS, INC., NORAMCO, INC., ENDO HEALTH SOLUTIONS, INC., ENDO PHARMACEUTICALS, INC., QUALITEST PHARMACEUTICALS, INC., ALLERGAN PLC, f/k/a ACTAVIS PLC, WATSON PHARMACEUTICALS, INC., n/k/a ACTAVIS, INC., WATSON LABORATORIES, INC., ACTAVIS LLC, ACTAVIS PHARMA, INC., f/k/a WATSON PHARMA, INC., MALLINCKRODT PLC and MALLINCKRODT LLC, for damages in excess of Seventy-Five Thousand Dollars (\$75,000), for interest, and for such other and further relief both at law and in equity to which Plaintiff may show to be justly entitled, and demand a trial by jury of all issues triable as a matter of right by a jury.

COUNT VII
CLAIM OF NEGLIGENCE
(AGAINST DISTRIBUTOR DEFENDANTS)

320. Plaintiff incorporates by reference the allegations contained in the preceding paragraphs.

321. The Distributor Defendants, MCKESSON CORPORATION, CARDINAL HEALTH INC., AMERISOURCEBERGEN DRUG CORPORATION, and ABBOTT LABORATORIES, INC., at all times material, had a duty to exercise reasonable care in the distribution of prescription opioids.

322. The Distributor Defendants breached their duty of care by failing to monitor and reduce the distribution and/or diversion of opioids.

323. The Distributor Defendants placed their profit motives above their legal duty and enabled, encouraged and caused the over-prescribing and distribution of opioids.

324. The Distributor Defendants negligently failed to perform their duty to help to prevent the over-prescription of opioids and/or acted with gross negligence.

325. The Plaintiff is without fault and it would not have paid millions of dollars in inappropriate prescriptions but for the wrongful conduct of the Distributor Defendants.

326. The Distributor Defendants were a proximate cause of the over-prescription of the opioids and, hence, the millions of dollars in inappropriate prescriptions paid for by Plaintiff.

WHEREFORE, Plaintiff, LABORERS 17 HEALTH BENEFIT FUND, prays for judgment against Defendants, MCKESSON CORPORATION, CARDINAL HEALTH INC., AMERISOURCEBERGEN DRUG CORPORATION, and ABBOTT LABORATORIES, INC., for damages in excess of Seventy-Five Thousand Dollars (\$75,000), for interest, and for such other and further relief both at law and in equity to which Plaintiff may show to be justly entitled, and demand a trial by jury of all issues triable as a matter of right by a jury.

DEMAND FOR JURY TRIAL

Plaintiff demands a trial by jury of all issues so triable as a matter of right.

DATED this 18th day of December, 2017.

Respectfully submitted,

*Attorneys for Plaintiff Trustees of the LABORERS 17
HEALTH BENEFIT FUND*

By: /s/ Daniel B. Rehns, Esq.

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